SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended			
2. **Request for Proposal (RFP) Number:** NIH-NIAID-DMID-08-26	3. **Issue Date:** August 24, 2007	4. **Just in Time:** [X]No [ ]Yes See Part IV Section L	5. **Set Aside:** [X]No [ ]Yes See Part IV Section L

6. Title : NIAID Division of Microbiology and Infectious Diseases: Clinical Agent and Speciman Repository

7. ISSUED BY:	8. SUBMIT OFFERS TO:
Office of Acquisitions National Institute of Allergy and Infectious Diseases National Institutes of Health 6700B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 4:00pm local time on December 21, 2007. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.

10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO TWO DIFFERENT LOCATIONS. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.

11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov

12. FOR INFORMATION CALL: Brian Jamieson
PHONE: 301-451-3678
e-MAIL: bj107xj@nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

Yvette R. Brown
Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases

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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this project is to provide DMID with Storage of Clinical Agents and Clinical Specimens. This initiative will cover a broad spectrum including:

- Receipt and Storage of Clinical Agents
- Labeling, Packaging and Repackaging of Clinical Agents
- Shipping Preparation Procedures and Equipment for Clinical Agents
- Shipping and Distribution of Clinical Agents
- Documents and Regulations for Shipping Clinical Agents.
- Tracking and Inventory of Clinical Agents
- Quarantine and Final Disposition of Clinical Agents
- Acquisition of Clinical Agents
  Receipt and Storage of Clinical Specimens
- Aliquoting and Labeling of Clinical Specimens
- Shipping and Distribution of Clinical Specimens
- Tracking and Inventory Management of Clinical Specimens
- Final Disposition of Clinical Specimens

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 27, 2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES ARTICLE in SECTION F.

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below.
Format of Cover page: All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address

1. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The report must also include the following sections:

a. Introduction: A section covering the purpose and scope of the contract effort.

b. Progress report: A section describing overall progress for each task or segment of work listed in the Statement of Work on which effort was expended during the reporting period. For example, the report shall include summaries or charts/graphs/tables on clinical agent shipments received from suppliers, clinical agent inventory, clinical agents shipped, returned clinical agents, clinical agents for disposition, clinical specimens received, aliquoting and labeling of clinical specimens, distribution of clinical specimens, clinical specimen inventory, final disposition of clinical specimens, data integrity, and changes/enhancements in electronic systems.

c. Personnel changes: A section covering any changes in personnel.

d. Problems and solutions: A section describing technical or performance problems encountered and corrective action taken. An explanation of any differences between planned and actual progress shall be included.

e. Financial report: A section describing the financial status and line item breakdown of direct cost expenditures of the contract, including personnel, materials, operating costs, travel, etc.

f. Maintenance of facilities, supplies and equipment: A section describing problems encountered and corrective action taken since the last monthly report.

A Monthly Progress Report shall not be due when the Semi-Annual Progress Report and Annual Progress Report are due.

2. Semi-Annual Progress Report

a. This report shall include a summation of the monthly progress reports and the activities planned for the ensuing reporting period. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

b. A Semi-Annual Progress Report shall not be due when the Annual Progress Report is due.

3. Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. This report shall include all of the sections provided in the Monthly Progress Report, an additional section to summarize all work conducted during the reporting period, and a section to address the anticipated work plan and budget for the coming year. An Annual Progress Report will not be required for the period when the Final Report is due.

4. Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract.

The Contractor shall provide the Project Officer and Contracting Officer with one copy each of the Final Report in draft form in accordance with the DELIVERIES Article in SECTION F of this contract 120 calendar days prior to the completion date of this contract. The Project Officer will review the draft report and provide the Contracting Officer with comments within 30 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

b. **Other Reports/Deliverables**

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

Source Code and Object Code - Use when software is used, produced, modified or enhanced

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural

Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisition
6700 B Rockledge Drive
MSC 7612, Room 3214
Bethesda, Maryland 20892- 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition as follows:

- Temperature controlled environment is required
- Shipments will be time sensitive/time critical
- International shipping will apply
- Shipping insurance is required
- Hazardous Materials shipping is applicable

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, The Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
6610 Rockledge Drive Room 6035
Bethesda, MD 20817

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause ***52.246-9, Inspection of Research and Development (Short Form)*** *(April 1984).*

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

Progress Reports:

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Progress Report	2 hard copies to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before 15th of the month. Thereafter, each report is due on/before the 15th of each month following each reporting period.
(2)	Semi-Annual Progress Report	2 hard copies to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before 15th of the month. Thereafter, each report is due on/before the 30th of the month following each 6-month period. Monthly reports will not be submitted the month the semi-annual report is due.
(3)	Annual Progress Report	2 hard copies to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before 30th of the month. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract. Monthly and semi-annual reports will not be submitted the month the annual report is due.
(4)	Draft Final and Final Report	2 hard copies to PO 1 original to CO 1 elec. copy to PO and CO	Draft Final Report is due 120 calendar days prior to the completion date of contract. Final Report is due on/before 60 days prior to the completion date of the contract.

Other Reports and Deliverables (Delivery Schedule):

Item	Description	SOW Reference	Recipient	Delivery Schedule
(1)	Draft Clinical Agent shipping request form	Item A.1.a.	PO	Within 5 business days of the effective date of the contract. Final shipping request form due within 5 business days of receiving PO comments
(2)	Notification of discrepancies or problems with clinical agents received Report	Item A.1.h.	PO	Within 24 hours of receipt.
(3)	Draft labeling, packaging, and repackaging request forms	Item A.2.a	PO	Within 5 business days of the effective date of the contract. Final labeling, packaging, and repackaging request form due within 5 business days of receiving PO comments.
(4)	Hard copy sample of labels	Item A.2.c	PO	Within 1 business day of request by the PO.
(5)	Sample of packaged, repackaged, or labeled clinical agent	Item A.2.g	PO	Within 1 business day of request by the PO.
(6)	Shipping Validation Study Reports	Item A.3.b.	PO	Within 30 business days of completion of the validation testing.
(7)	Clinical Agent shipping information downloaded from electronic monitoring devices	Item A.4.i	PO	Upon request of PO
(8)	Clinical Agent specific Regulatory Requirements for shipment to non-domestic sites	Item A.5.b	PO	Upon request of PO
(9)	Draft Onsite Disposition Plan	Item A.7.b	PO	Within 30 business days of contract award

(10)	Final Onsite Disposition Plan	Item A.7.b	PO	Within 10 business days of receipt of PO comments on draft Onsite Disposition Plan.
(11)	Written notifications of clinical agents to be returned	Item A.7.d.	PO	Within 2 business days of becoming aware of return.
(12)	Clinical Agent Final Study Disposition Report	Item A.7.h	PO	Within 5 business days of close out of a study.
(13)	Final Non-Clinical Study Report	Item A.8.d	PO	Within 10 business days of completion of non-clinical testing of acquired clinical agents
(14)	Draft Clinical Specimen shipping request form	Item B.1.a	PO	Within 5 business days of the effective date of the contract. Final shipping request form due within 5 business days of receiving PO comments
(15)	Notification of discrepancies or problems with clinical specimans received	Item B.1.d	PO	Within 24 hours of receipt.
(16)	Clinical Specimen Receipt Form	Item B.3.d	PO	Within 5 business days of the effective date of the contract. Final shipping receipt form due within 5 business days of receiving PO comments.
(17)	Inventory Report	Item B.4.b	PO	Within 10 business days of completing physical inventory.
(18)	Written notification of 2 year expiration date for clinical specimens	Item B.5.a	PO	Within 30 business days of storage expiration.
(19)	Plan for Transfer of Clinical Agents and Clinical Speciments in Case of Disaster	Item C.1.k	PO	Draft due within 30 business days of the effective date of contract. Final due within 5 business days of receipt of PO comments.

(20)	Assessment and written recommendations for modifications and improvements to CARIM	Item C.2.a.iv	PO Include CO, if software development recommended	Within 60 business days of the effective date of the contract.
(21)	Draft Data Validation Plan to ensure data integrity of CARIM	Item C.2.b.iii	PO	Within 30 business days of the effective date of the contract. Final Data Validation Plan due within 10 business days of receipt of PO comments.
(22)	Information System Security Plan (ISSP)	Item C.2.c	PO NIAID Information System Security Officer (ISSO)	Within 20 business days of the effective date of the contract
(23)	Risk Analysis	Item C.2.c.iv	PO	Initially due with item 22, ISSP. Thereafter, every 3 years
(24)	Continuity of Operations Plan	Item C.2.c.v	PO	Initially due with item 22, ISSP. Thereafter, every 6 months
(25)	Draft Quality Assurance/Quality Control (QA/QC) Plan	Item C.4.i and C.4.a.ii	PO	Within 15 business days of the effective date of the contract. Final QA/QC Plan due within 10 business days of receipt of PO comments
(26)	List of all SOPs for operations listed in the SOW	Item C.4.a.i	PO	Within 30 days of the effective date of contract. Updates due within 30 business days of modification.
(27)	Interim and Final audit reports	Item C.4.b.iii	PO	Within 20 business days of the completion of the audit of site visit.
(28)	Meeting Summary of the Contract Initiation Meeting	Item C.5.b.i	PO	Within 3 business days of the meeting.

(29)	Agenda and background material for Weekly Progress meetings/ teleconferences	Item C.5.b.ii	PO	Within 2 business days in advance of meeting.
(30)	Written summary of weekly progress meetings/ teleconferences	Item C.5.b.ii	PO	Within 5 business days of the conclusion of meeting.
(31)	Agenda and background material for Annual meetings	Item C.5.b.iii	PO	Within 10 business days in advance of meeting..
(32)	Written summary of Annual meeting	Item C.5.b.iii	PO	Within 5 business days of the conclusion of meeting.
(33)	Presentation materials and ad hoc reports on other meetings	Item C.5.b.iv	PO	Presentation material 5 days prior to the meeting, and ad hoc reports within 5 business days of the conclusion of meeting.
(34)	Draft Initial Transition Plan	Item C.6.a.ii	PO	Within 15 business days of the contract effective date. Final Initial Transition Plan due within 10 business days of receipt of PO comments
(35)	Initial Transition Report	Item C.6.a.v	PO	Within 30 business days of initial transition completion.
(36)	Draft Final Transition Plan	Item C.6.b.ii	PO	Due 1 year prior to completion date of contract. Final Transition Plan due 10 months prior to completion date of contract.
(37)	Final Transition Report	Item C.6.b.iv	PO	Within 20 business days prior to the completion date of contract.
(38)	Plan to implement Contract Options	Item D.1	PO	Due 30 days prior to exercising options

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

1. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

    a. Payment requests shall be submitted as follows:
    One original to the following designated billing office:

        National Institutes of Health
        Office of Financial Management
        Commercial Accounts
        2115 East Jefferson Street, Room 4B-432, MSC 8500
        Bethesda, MD 20892-8500

b. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

i. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is NIAID.

ii. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices.

iii. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. (Note: This only applies to new contracts awarded on/after June 4, 2007, and any existing contract modified to include the number.)

iv. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

v. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a two-way match.

vi. Inquiries regarding payment shall be directed to the designated billing office, (301) 496--6088.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted 3 years from contract award.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.2. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

   Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.3. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.4. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.

Public Law and Section No.	Fiscal Year	Period Covered

[applicable information to be included at award]

ARTICLE H.5. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.6. PRIVACY ACT, HHSAR 352.270-12 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number _____. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm.

ARTICLE H.7. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F & A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

Public Law and Section No.*	Fiscal Year*	Dollar Amount of Salary Limitation*

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

[*Applicable information to be included at award]

ARTICLE H.9. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements: Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

ARTICLE H.10. CONFIDENTIALITY OF INFORMATION

The following information is covered by **HHSAR 352.224-70, Confidentiality of Information** (January 2006).

ARTICLE H.11. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. _____"

ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.13. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http://ott.od.nih.gov/NewPages/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

Sharing of Model Organisms for Biomedical Research

The contractor's plan for sharing model organisms, dated TBD, is hereby incorporated by reference. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan

ARTICLE H.14. SHARING RESEARCH DATA

The contractor's data sharing plan, dated TBD is hereby incorporated by reference. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.15. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer Select Agents under this contract, before using NIH funds for any work directly involving the Select Agents, the

foreign institution must provide information satisfactory to the NIAID, NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf). The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/index.html and: http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html
For foreign institutions, see the NIAID Select Agent Award information: (http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

ARTICLE H.16. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://www.usfa.fema.gov/hotel/index.htm.

ARTICLE H.17. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.18. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the

author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

ARTICLE H.19. CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:
http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

a. ***Alternate IV*** *(October 1997) of FAR Clause* ***52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications*** *(October 1997) is added.*

b. ***Alternate II*** *(October 2001) of FAR Clause* ***52.219-9, Small Business Subcontracting Plan*** *(September 2006) is added.*

c. *FAR Clause* ***52.232-20, Limitation Of Cost*** *(April 1984), is deleted in its entirety and FAR Clause* ***52.232-22, Limitation Of Funds*** *(April 1984) is substituted therefor.* ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

   "....The Contracting Officer may exercise the option by written notice to the Contractor within 60 days calender days...."

2. FAR Clause **52.217-8, Option to Extend Services** (November 1999).

   "..The Contracting Officer may exercise the option by written notice to the Contractor within 60 calender days.

3. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

   "(a) The Government may extend the term of this contract by written notice to the Contractor within 60 calender days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 calender days before the contract expires. The preliminary notice does not commit the Government to an extension."

   "(b) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 9 years"

4. *FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).*

   "(c) Waiver of evaluation preference.....
   ***[ ]** Offeror elects to waive the evaluation preference."*

5. *FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).*

6. *FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).*

7. *FAR Clause **52.224-1, Privacy Act Notification** (April 1984).*

8. *FAR Clause **52.224-2, Privacy Act** (April 1984).*

9. *FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (June 2000).*

10. *FAR Clause **52.227-14, Rights in Data - General** (June 1987).*

11. **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

    Specific data items that are not subject to paragraph (j) include: NONE

12. *FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).*

13. *FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).*

14. *FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).*

15. *FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).*

16. *FAR Clause **52.251-1, Government Supply Sources** (April 1984).*

b. *DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:*

    1. *HHSAR Clause **352.223-70, Safety and Health** (January 2006).*

    2. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*

    3. *HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).*

c. *NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:*

    The following clauses are attached and made a part of this contract:

    1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. *FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)*

(a) Definition. As used in this clause --

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts

in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1)Contractors and subcontractors that employ fewer than 15 persons;

(2)Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4)Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.
(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	http://www.niaid.nih.gov/contract/eproposal.htm#pack
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.pdf
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Additional Technical Proposal Intructions, Format for Technical Proposal, and Table of Contents	See Attachment Section at end of this RFP
Attachment 5:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at end of this RFP
Attachment 6:	Additional RFP Materials	See Attachment Section at end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 10:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Small Business Subcontracting Plan	rcb.cancer.gov/rcb-internet/forms/SBA Plan Nov 2005.pdf
Attachment 13:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 14:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 17:	Privacy Act System of Records	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet.nci.nih.gov/forms/safety&health-1-06.pdf
Attachment 19:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 20:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 21:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 22:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 23:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and
2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. **GENERAL INFORMATION**

a. ***INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION*** *[FAR Provision 52.215-1 (January 2006)]*

(a) Definitions. As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals.

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.
Submission, modification, revision, and withdrawal of proposals. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(3) Submission, modification, revision, and withdrawal of proposals.

(i)Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.
(End of Provision)

Alternate I (*October 1997).As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:*

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**
Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541990.
2. The small business size standard is $6.5 Million.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **TYPE OF CONTRACT AND NUMBER OF AWARDS**
It is anticipated that a single award will be made from this solicitation and that the award(s) will be made on/about August 21, 2008.
It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Term of 7 years with one 2 year option and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. **ESTIMATE OF EFFORT**
It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 11 FTEs per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**
Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

g. **RELEASE OF INFORMATION**
Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**
You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

i. **PREPARATION COSTS**
This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Charles Grewe, Director
Office of Acquisitions
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700 B Rockledge Drive Room 3214
Bethesda, MD 20892- 7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.
(End of Provision)

k. ***LATE PROPOSALS AND REVISIONS****, HHSAR 352.215-70 (January 2006)*
Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it appears to offer the best value to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.
(End of provision)

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. **Contract Type and General Clauses**

   It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. **Authorized Official and Submission of Proposal**

   The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

   I. COVER PAGE

      Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

   II. TECHNICAL PROPOSAL

      It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

   III. BUSINESS PROPOSAL

      It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. **Proposal Summary and Data Record (NIH-2043)**

   The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. **Separation of Technical and Business Proposals**

   The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**
   You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. **Evaluation of Proposals**
   The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

7. **Potential Award Without Discussions**
   The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. **Use of the Metric System of Measurement**
   It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.
   The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:
   Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).
   Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.
   Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

9. **Standards for Privacy of Individually Identifiable Health Information**
   The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.
   Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

10. **Privacy Act - Treatment of Proposal Information**
    The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

11. **Selection of Offerors**

a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

   Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

   While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient

competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f. The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

12. **Institutional Responsibility Regarding Conflicting Interests of Investigators**

- **EACH INSTITUTION MUST:**

a. Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

b. Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

c. Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

e. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

f. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

g. Certify, in each application/proposal for funding to which the regulations applies, that:

1. there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
2. prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
3. the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
4. the Institution will otherwise comply with the regulations.

- **Institutional Management of Conflicting Interests**

a. The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**
Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i. public disclosure of significant financial interests;
ii. monitoring of research by independent reviewers;
iii. modification of the research plan;
iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
v. divestiture of significant financial interests; or
vi. severance of relationships that create actual or potential conflicts of interests.

b. An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

13. **ROTC Access and Federal Military Recruiting on Campus**
Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.
Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for

purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

14. **Past Performance Information**

a. Offerors shall submit the following information as part of their Business proposal.
A list of the last 3 contracts completed during the past Three years and THE LAST 5 CONTRACTS AWARDED currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as first tier subcontractor.
Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code
The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

15. ***Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2006)***
Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by Public Law 105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, procurement, maintenance, and/or use of EIT products/services; therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards. Information about Section 508 is available at http://www.section508.gov/.

(End of provision)

16. ***Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)***
This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.
FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

    a. *Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).*

    b. *Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*

    c. *Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).*

b. **TECHNICAL PROPOSAL INSTRUCTIONS**
A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

1. **Technical Discussions**
The technical discussion included in the technical proposal should respond to the items set forth below:

    a. **Project Objectives, NIH-1688-1**
    The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

        - For an **Institution of Higher Education**: The form MUST be completed in its entirety.
        - For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.
        The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, " **INSTRUCTIONS** :"

    b. **Statement of Work**

        1. Objectives
        State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project

and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach
   Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods
   Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule
   Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

1. Single Principal Investigator/Project Director
   List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Other Investigators
   List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

   List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

   - The specific items or expertise they will provide.
   - Their availability to the project and the amount of time anticipated.
   - Willingness to act as a consultant.
   - How rights to publications and patents will be handled.

4. Resumes

   Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. **Technical Evaluation**

   Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

3. **Additional Technical Proposal Information**

   a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

   b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4. **Other Considerations**

   Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

   a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

   b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

   c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

   d. Other factors you feel are important and support your proposed research.

   e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

5. Offerors should submit all technical questions concerning this solicitation in writing to the contract specialist. NIIAID should receive all questions no later than 45 calendar days after the date of this solicitation. NIAID will answer questions which may affect offers in an amendment to the solicitation. NIAID will not reference the source of the questions.

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**
   The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Proposal Cover Sheet**
   The following information shall be provided on the first page of your pricing proposal:

   1. Solicitation, contract, and/or modification number;
   2. Name and address of Offeror;
   3. Name and telephone number of point of contact;
   4. Name, address, and telephone number of Contract Administration Office, (if available);
   5. Name, address, and telephone number of Audit Office (if available);
   6. Proposed cost and/or price; profit or fee (as applicable); and total;
   7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
   8. Date of submission; and
   9. Name, title and signature of authorized representative.
      This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

3. **Information Other than Cost or Pricing Data**

   a. The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.
      Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

b. The information submitted shall be at the level of detail described below.

1. **Direct Labor**
   Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**
   Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**
   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**
   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**
   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**
   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**
   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**
   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**
   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**
    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

4. ***Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20*** *(October 1997)]*

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15 2 of FAR 15.408.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406 2.
(End of provision)

5. **Salary Rate Limitation in Fiscal Year 2007**
Offerors are advised that pursuant to P.L. 110-005**, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any

contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 110-005** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 110-005** states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/07tables/html/ex.asp

***Note to Offerors**: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.

***Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY 2007. The Executive Level I annual salary rate was $183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive Level I salary rate increased to $186,600.*

6. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c. The offeror understands that:

1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small

Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

4. A description of the method used to develop the subcontracting goals.

5. A description of the method used to identify potential sources for solicitation purposes.

6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.

10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

    For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

    HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

    23% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

7. **HUBZone Small Business Concerns**

   Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

8. **Extent of Small Disadvantaged Business Participation**

   In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

   The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

   The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

   The Department of Commerce website for the annual determination for NAICS codes* is: http://www.arnet.gov/References/sdbadjustments.htm.

   * *Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

   Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

9. **Total Compensation Plan**

   a. **Instructions**

      1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors, as part of their business proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
      2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
      3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

   b. **Evaluation**

      1. **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**
   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**
   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**
   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

10. **Qualifications of the Offeror**
    You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

    a. **General Experience**
       General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

    b. **Organizational Experience Related to the RFP**
       Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

    c. **Performance History**
       Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

    d. **Pertinent Contracts**
       Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost

performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

11. **Other Administrative Data**

a. **Property**

1. It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

    a. An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

    b. No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

2. The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

3. The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b. ***Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38*** *(MAY 1999)*

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.

(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.
(End of Provision)

c. **Financial Capacity**
The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. **Incremental Funding**
An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:
Incremental Funding, HHSAR 352.232-75 (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.
(End of provision)

e. ***Facilities Capital Cost of Money****, FAR 52.215-16, (June 2003)*
(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.
(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ]Fac Cap Cost of Money (Has)*The prospective Contractor* ***has*** *specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).*

[ ]Fac Cap Cost of Money (Has Not) ***has not*** *specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

12. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).

b. What priority the work will be given and how it will relate to other work.

c. The amount of time and facilities available to this project.

d. Information on their cognizant field audit offices.

e. How rights to publications and patents are to be handled.

f. A complete cost proposal in the same format as the offeror's cost proposal.
Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

13. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

14. **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

15. **Travel Costs/Travel Policy**

a. **Travel Policy**
One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

16. **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and the Extent of Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and Extent of SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

2. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO ATTACHMENT 4 - Additional Technical Proposal Instructions - OF THIS SOLICIATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF PROPOSALS. MANDATORY QUALITIFCATION CRITERIA

The Mandatory Qualification Criteria establish conditions that must be met at the time of receipt of the Original Proposal in the Office of Acquisitions, NIAID, in order for your proposal to be considered any further for award. Listed below are the Mandatory Qualification Criteria. The offeror must include all information that documents and/or supports the Mandatory Qualification Criteria in one clearly marked section at the front of the Technical Proposal. Technical Proposals that are determined by the Project Officer not to meet the Mandatory Qualification Criteria will not be submitted for peer review and will not be considered any further for award.

Mandatory Qualification Criteria:

Criterion 1. Offeror(s) must possess a permit to purchase, import, distribute and export drug.

Criterion 2. Offeror(s) must include a licensed pharmacist as part of the proposed staff.

Justification for Mandatory Qualification Criteria:

In order to perform the tasks described in the SOW, the facility must have a permit to purchase and distribute clinical agents, and there must be a licensed pharmacist on site.

Documentation Required to Support Having Met the Mandatory Qualification Criteria:

1. A copy of the current facility permit to purchase, import, distribute and export drug must be included in the Technical Proposal.

2. A copy of the current license for the proposed pharmacist must be included in the Technical Proposal.

PRE-AWARD SITE VISIT OR SITE AUDIT

Offerors determined, upon completion of the scientific/technical peer review, to be in the Competitive Range may be subject to auditing of their facilities and Quality Assurance and Quality Control (QA/QC) capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be a factor in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

TECHNICAL EVALUATION CRITERIA:

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions - OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

CRITERIA	**WEIGHT**
CRITERION 1: TECHNICAL APPROACH	**40**

Soundness, adequacy, appropriateness, and feasibility of the proposed technical approaches, plans and procedures, and technical understanding of the requirements of the Statement of Work with respect to:

A. Clinical Agents:

Management and operation of a clinical agent repository including proposed plans and procedures to receive, inspect, appropriately store, monitor, and track clinical agents received from suppliers; label, package, and repackage clinical agents for distribution; validate packing and shipping procedures; ship clinical agents to clinical research sites and DMID-approved testing laboratories; generate and obtain shipping documents; track and monitor inventory; quarantine and dispose of returned, unused, expired and/or recalled clinical agents; and acquire and perform non-clinical testing on acquired clinical agents. Relevance of recent organizational experience with clinical agent receipt, storage, and distribution with respect to the scope of clinical research to be supported under the contract; organizational experience with clinical agent repository activities including problems encountered and strategies used to resolve the problems; and examples of non-clinical testing on clinical agents performed by either the offeror or proposed subcontractors.

B. Clinical Specimens:

Management and operation of a clinical specimen repository, including proposed plans and procedures to receive, inspect, appropriately store, monitor, and track clinical specimens received from DMID-funded clinical research sites; aliquot and label clinical specimens for distribution; ship samples to DMID-funded and DMID-approved testing laboratories; track and monitor inventory; and dispose of clinical specimens in compliance with all public and occupational health, safety and environmental protection regulations. Relevance of organizational experience with clinical specimen receipt, storage, and distribution with respect to the scope of clinical research to be supported under the contract; and organizational experience with clinical specimen repository activities including problems encountered and strategies used to resolve the problems.

C. Electronic Information Systems, Data Management, and System Security

1. Proposed plan for and organizational experience in managing and operating database information systems, including software and hardware used by the offeror and all proposed subcontractors for projects of the same or similar scope, complexity and requirements, and problems encountered in system maintenance, operation and security.

2. Proposed plan for investigating new and improved technologies to enhance the efficiency and ease of use of the existing database systems.

3. Proposed plan for and organizational experience in coordinating clinical repository functions with other clinical research support contractors with respect to verifying and tracking regulatory status of clinical agents and receipt of regulatory documents from clinical research sites, and identifying and tracking clinical specimens received.

4. Organizational experience with and proposed plan for meeting NIH Information System Security requirements and DHHS Automated Information Systems Security Program requirements.

D. Quality Assurance/Quality Control (QA/QC):

Proposed QA/QC Plan to standardize contract processes and ensure that the conduct of all activities complies with domestic and non-domestic regulations and requirements including: SOP template and list of SOPs for all operations outlined in the Statement of Work including procedures for maintenance of version control; plans for providing and documenting training for Contractor and subcontractor personnel spanning the breadth of contract requirements; procedures for maintenance and validation status of equipment and computer software; plans for maintaining and documenting facility accreditations; plans for documenting adherence to all applicable requirements and guidelines; and record retention and storage procedures. Proposed plans to arrange for site visits and accommodate independent audits to evaluate Contractor and subcontractor facilities for compliance with domestic and non-domestic laws and regulations, FDA regulations and guidances, including those required to meet cGMP, GLP, and GCP standards, DMID policies, and the terms of the contract.

E. Initial and Final Transition:

Adequacy and appropriateness of the proposed plans for the initial and final transition of contract materials, databases and equipment, including approaches to ensure that there is no loss of time or interruption to the conduct of ongoing DMID-funded clinical research and clinical research in development during the transition period.

CRITERION 2: FACILITIES, EQUIPMENT, SAFETY, TRAINING AND OTHER RESOURCES 25

The availability, adequacy and suitability of facilities, equipment and other resources of the offeror and all proposed subcontractors for the safe and secure operation and maintenance of the CASR as demonstrated by the following:

A. Location and features of the proposed facilities, including a detailed floor plan of the proposed facilities showing the location, and providing a detailed description of, equipment, clean room(s), offices, shipping docks, freezers, refrigerators, quarantine areas, storage areas, packaging areas, labeling areas, and processing, returns, and archival space for carrying out the requirements of the Statement of Work.

B. Documentation regarding ownership or lease of the proposed facilities demonstrating availability at the initiation of, and for the duration of the contract.

C. Plan for compliance with all safety guidelines and regulations including training and monitoring of personnel for exposure to infectious and other hazardous agents and materials.

D. Plan for compliance with cGMP, GLP and GCP.

E. Proposed physical and electronic security systems for the facility, including systems to prevent unauthorized access to the CASR databases and computer related systems.

F. Plan for the transfer of clinical agents and clinical specimens to appropriate storage conditions in the event of power failure, fire, flood, or other occurrences capable of damaging clinical agents or clinical specimens.

CRITERION 3: SCIENTIFIC AND TECHNICAL PERSONNEL 20

A. Principal Investigator

Appropriateness and adequacy of the education, training, experience, expertise, qualifications and availability of the proposed PI, including experience with projects of comparable size and complexity with respect to the following:

1. Management and operation of a clinical agent and clinical specimen repository in accordance with applicable regulations;

2. Coordination, management, and QA/QC for projects of similar size and complexity;

3. Identifying issues, prioritizing projects, and identifying qualified personnel to carry out repository functions;

4. Interacting with a variety of clinical research site staff, industry and the NIH;

5. Providing technical assistance, training, and oversight related to safety and technical procedures for clinical agents and clinical specimens handling.

B. Other Scientific and Technical Personnel

Appropriateness and adequacy of the education, training, experience, expertise, qualifications, and availability of the proposed scientific and technical personnel of the offeror and all proposed consultants/subcontractors, including experience with projects of similar size and complexity and the adequacy of the proposed mix of staff, expertise, experience and training, with respect to: (i) repository technicians; (ii) laboratory technicians; (iii) information technology staff; (iv) quality assurance/quality control staff; and (v) staff trained in domestic and non-domestic regulations; and certified for shipping and handling biohazardous materials.

CRITERION 4: PROJECT MANAGEMENT **15**

A. Adequacy of the plans for the staffing, organization, distribution of responsibilities, leadership, coordination and lines of authority for carrying out contract requirements.

B. Suitability of systems proposed for tracking contract activities and monitoring progress, timelines and budgets.

C. Suitability of plan for how the PI will communicate with the Project Officer and Contracting Officer, as well as established lines of communication with product manufacturers, clinical study sites, and other DMID clinical research support contractors.

D. Suitability of the plan for safeguarding the confidentiality and intellectual property of data and materials provided under the contract.

TOTAL POSSIBLE WEIGHT: **100**

EVALUATION OF OPTIONS **20**

A. Option 1. Increased Clinical Specimen Capacity Soundness and feasibility of proposed plans to implement increased clinical specimen capacity at the CASR.

B. Option 2. Increased Length of Time for Storage of Clinical Specimens Soundness and feasibility of proposed plans to implement additional clinical specimen storage at the CASR, beyond the two-year short-term storage required during the base period of performance.

TOTAL POSSIBLE WEIGHT (with Options): **120**

3. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechnical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

4. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified

b. Extent of commitment to use SDB concerns

STATEMENT OF WORK

BACKGROUND AND INTRODUCTION:

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat and ultimately prevent the myriad of infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents other than Human Immunodeficiency Virus. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which is funded through a variety of research grants and contracts.

The evaluation of new and improved vaccine and therapeutic candidates in clinical trials and clinical studies is an essential element of DMID's efforts. Through an extensive network of grant and contract research programs, DMID supports a broad range of clinical research, including single-site and multi-center Phase 1, Phase 2, and Phase 3 (and occasionally Phase 4) clinical trials for the evaluation of bacterial, viral and parasitic vaccines, other biologics, and drugs as preventive and therapeutic measures against infectious diseases in people of all ages and risk categories. Much of this clinical research is devoted to addressing critical public health needs, such as those related to emerging and re-emerging infectious diseases, including avian influenza and West Nile Virus, and those supporting the evaluation of safety and efficacy of vaccine and therapeutic candidates against potential agents of bioterrorism, including NIAID priority biodefense pathogens (http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm),

In August 2000, NIAID awarded a 7-year contract to Fisher BioServices Corporation (N01-AI-05413) to provide a wide variety of regulatory support services for DMID clinical research activities, including clinical site monitoring, management and preparation of regulatory files, and management and operation of a clinical agent and clinical specimen repository. This contract provides for the establishment and operation of a Clinical Agent and Specimen Repository (CASR) that adheres to current Good Manufacturing Practice (cGMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP) for the acquisition, receipt, storage and shipping of clinical agents and clinical specimens in support of DMID-sponsored clinical trials and research programs in the U.S. and abroad. Regulatory support services are currently being recompeted through a separate contract solicitation, RFP NIH-NIAID-DMID-08-05.

Clinical agents include investigational study products (drugs, vaccines, and therapeutics), commercial products, placebos, syringes, and other protocol-mandated supplies to be used in DMID-sponsored clinical trials. For the purposes of this contract, other protocol-mandated supplies include electronic adherence measuring devices and associated devices for downloading data, thermometers, oral syringes, adaptors for transferring liquids from bottles to syringes, syringes for injection, and pregnancy test kits. Clinical specimens include sera or other protocol-mandated specimens obtained from DMID-funded clinical research sites, to be distributed to DMID-approved testing laboratories for analysis.

The current DMID Regulatory Affairs Support contractor will provide the Contractor with the existing DMID-owned Clinical Agent Repository Inventory Management (CARIM)

Database System and access to the electronic ordering module (Order It Module) within the Regulatory Affairs Support contract database, Human Subjects Research Oversight Accountability Database (HSROAD), another DMID-owned database. The CARIM database is used in conjunction with HSROAD. The Order It Module, ORDER IT, allows DMID staff to request shipping of clinical agents and clinical specimens from the repository to clinical sites and laboratories. In addition to ordering shipments, ORDER IT provides for authorization from responsible DMID staff and verification of regulatory compliance for the distribution of clinical agents to DMID-funded clinical research sites. The system features limited access for persons with permissions under specific protocols. Both databases are currently being managed by the DMID Regulatory Affairs Support contractor.

NIAID recognizes that a single organization or institution may not have the expertise and facilities required to perform all of the activities set forth in the Statement of Work and, consequently, that the Contractor may need to be supported to a certain extent by the expertise and resources of subcontractors to perform some of the tasks required. However, the Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

SCOPE:

This contract will consist of a base period of seven (7) years for the management and operation of a cGMP-compliant clinical agent and clinical specimen repository to include receipt, storage, aliquoting, labeling, packaging, repackaging, shipping, acquiring, and disposing of clinical agents and clinical specimens. Options to: (i) increase the clinical specimen capacity, (ii) increase the length of time for which clinical specimens may be held beyond the specified short-term, two-year period, or (iii) extend the contract to continue the services required during the base period for up to an additional two (2) years, may be exercised at the discretion of the Government.

The Contractor shall coordinate efforts and collaborate with the DMID Regulatory Affairs Support contractor, the DMID Clinical Trials Management (CTM) contractor, the DMID Statistical and Data Coordinating Center (SDCC) contractor**,** and other DMID-supported contractors and grantees involved in the conduct of clinical research.

TECHNICAL REQUIREMENTS:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work set forth below. Specifically the Contractor shall perform the following:

A. CLINICAL AGENTS

1. Receipt and Storage of Clinical Agents

Receive and store clinical agents from product suppliers in support of DMID-funded clinical research through carrying out the following functions specified below. Shipments of clinical agents shall be received from a variety of sources, including: domestic pharmaceutical manufacturers; pharmaceutical packaging firms that manufacture and/or package non-commercially available clinical agents under

contract to DMID; commercial pharmaceutical companies; and non-domestic pharmaceutical suppliers.

a. Develop, following specifications provided by the Project Officer, an electronic clinical agent shipping request form for the Project Officer to use in reviewing and approving requests from suppliers to ship clinical agents to the CASR. Provide a draft shipping request form to the Project Officer for review and approval within 5 business days of the effective date of the contract. The Project Officer will provide comments within 3 business days of receipt of the form. Revise the form in accordance with Project Officer comments, and submit the final shipping request form to the Project Officer within 5 business days of receipt of Project Officer comments. The Project Officer will provide the shipping request form to the clinical agent supplier for use to request shipment of clinical agents to the CASR. Requests will be submitted to the Project Officer for approval. The Project Officer will provide the Contractor with an electronic copy of the approved clinical agent shipping request.
b. Upon receipt of the Project Officer-approved clinical agent shipping request, verify the regulatory status of the clinical agent using regulatory information obtained from the Regulatory Affairs Support database (see SOW reference C.2.b.ii).
c. Coordinate with the supplier to arrange shipment of the clinical agent to the CASR. Provide written instructions to the supplier outlining appropriate shipping and handling requirements.
d. Obtain all required import permits and authorizations for receiving, storing and distributing clinical agents.
e. Provide loading dock access and necessary equipment to receive, transport, and store large shipments.
f. Provide storage facilities to accommodate the following specifications for clinical agents:

    - -194^{o}C, 4 - 6 tanks with a capacity to hold approximately 50,000 vials
    - -80^{o}C, (approximately 1,400 cu. ft.)
    - -20^{o}C, (approximately 14,000 cu. ft.)
    - 2 to 8^{o}C, (approximately 10,000 cu. ft.)
    - Controlled room temperature, (approximately 2,500 cu. ft.)

g. Perform a 100% documented inspection of all clinical agent shipments received including labeling, and primary and secondary packaging. Reconcile shipments received with shipping lists and notify the Project Officer of any discrepancies or problems with the shipment by e-mail within 24 hours of identifying a discrepancy or problem.
h. Notify suppliers within 24 hours of shipment receipt of all discrepancies found for each shipment and request corrective action be taken within 3 business days. Verify corrective actions performed by suppliers within 3 business days of electronic receipt of the request for corrective action.
i. Track and record contents and condition of the shipments. Electronically document chain of custody, shipment receipt date, and condition and inspection of clinical agents and shipments. Provide a summary report of clinical agent shipments received in the Monthly Progress Reports.

j. Ensure that a legible Certificate of Analysis (CoA) or other DMID-approved product information document is available for each lot of clinical agent, obtained either from the product manufacturers or directly from the Project Officer. Review the CoA received from the product manufacturer for completeness and accuracy prior to submission to the Project Officer. If issues are identified in the CoA by the Contractor such as discrepancies with the lot numbers, descriptions, specifications versus results, potency, or units of measurement indicated, the Contractor must consult with the clinical agent manufacturer to resolve all discrepancies and notify the Project Officer once the issues are resolved. Retain all original clinical agent-related documents for the duration of the contract.
k. Store clinical agents under conditions indicated by the manufacturer, monitor and document that these conditions are consistently maintained.

2. Labeling, Packaging and Repackaging of Clinical Agents

Label, package and/or repackage clinical agents for distribution to DMID-funded clinical research sites and DMID-approved testing laboratories as specified by the Project Officer.

a. Develop, following specifications provided by the Project Officer, an electronic request form for Project Officer use in reviewing and approving requests from DMID-funded clinical research sites for labeling, packaging and/or repackaging of clinical agents. Provide a draft request form to the Project Officer for review and approval within 5 business days of the effective date of the contract. Revise the form in accordance with Project Officer comments, and submit a final request form to the Project Officer within 5 business days of receipt of Project Officer comments.
b. Provide equipment and supplies needed to design and generate appropriate labels for clinical agents. This includes special labeling requirements such as those required for certain vaccine vials for ability to withstand -80°C storage, over-labeling, and tear off labels. Other labeling requirements include: labeling envelopes containing medication patches or other study use materials; assembling custom kits; labeling gel packets; labeling and re-labeling products “Not for Human Use;” labeling according to subject specific randomization scheme; and labeling secondary packaging. Label preparation may be carried out by subcontractors; however the actual labeling of clinical agents must be performed at the prime Contractor’s facility.
c. Provide a hardcopy sample of all labels to the Project Officer for review and approval prior to affixing to a clinical agent. These label samples shall be submitted to the Project Officer for review either the same day they are generated or, at the latest, the day following receipt of the request from the Project Officer. The Project Officer will provide comments within 2 business days of receipt of label samples. Provide a new version of a label, based on feedback from the Project Officer, until an approved version is produced.
d. Affix primary or auxiliary labels on clinical agents and on secondary packaging.
e. Provide and maintain the necessary clean room(s) and equipment for packaging and repackaging of clinical agents, as well as facility space to label under cold chain conditions in compliance with cGMP.
f. Provide subject-specific, unit-of-use packaging, including vials, blister packaging, for solids, liquids, injections, topical, and powder dosage forms, when required by the protocol.

g. Provide one sample, if requested, of each of the repackaged, labeled clinical agents to the Project Officer for approval prior to completion of labeling functions and prior to the distribution to the DMID-funded clinical research sites and DMID-approved testing laboratories. These samples shall be submitted to the Project Officer for review either the same day they are generated or, at the latest, the day following receipt of the request from the Project Officer. The Project Officer will provide comments within 2 business days of receipt of the sample. If samples are not approved by the Project Officer, corrections shall be made until the Project Officer approves the sample.

3. Shipping Preparation Procedures and Equipment for Clinical Agents

Ensure the adequacy of shipping and packaging procedures and equipment through carrying out the following functions:

a. Within 10 business days of receipt of request from the Project Officer, conduct validation testing of the procedures for the packaging and shipping of clinical agents under appropriate temperature conditions ranging from -194°C to controlled room temperature, U.S. Pharmacopeia (USP) specified conditions, as well as the conditions required for controlled substances (as defined by the U.S. Drug Enforcement Agency), biologics, ethanol-containing products, electronic devices, infectious agents, hazardous goods, and for products sensitive to air pressure, humidity, vibrations, and carbon dioxide.
b. Within 30 business days of completion of each validation testing, prepare and submit to the Project Officer, a Shipping Validation Study Report. Ensure that the summary data presented in these reports are traceable to the original, unaltered data.
c. Provide the equipment to prepare shipments of clinical agents for both domestic and non-domestic DMID-funded clinical research sites and DMID-approved testing laboratories.

4. Shipping and Distribution of Clinical Agents

Upon Project Officer approval, ship and distribute clinical agents to DMID-funded clinical research sites and DMID-approved testing laboratories, in compliance with IND (Investigational New Drug) regulations, domestic and non-domestic regulations and DMID policies.

a. Prior to processing and shipping a clinical agent request, verify the following:

    i. Inventory is available for release;
    ii. Project Officer or designee authorized by the Project Officer has approved the request;
    iii. Appropriate and current import/export permits are in place at the CASR;
    iv. Regulatory documents for the clinical agent have been received by DMID (see SOW reference C.2.b);
    v. For shipments to DMID-funded clinical research sites, that the site has been approved for initiation of the clinical trial (see SOW reference C.2.b.)

b. Identify freight forwarders, couriers, and customs brokers for shipping clinical agents that meet the needs of the clinical agent based on destination, protection required for the clinical agents and performance history.
c. Fill orders with appropriate protocol-specific clinical agents for subsequent packing and shipping. Ship clinical agents to DMID-funded domestic and non-domestic clinical research sites and DMID-approved testing laboratories, so that shipments are routinely received in the U.S. within 24 hours and internationally within 3-5 calendar days.
d. Provide shipping cartons, customized boxes, cushioning materials, appropriate labels, sealing tape, insulation materials, validated shipping containers, and all other supplies to ensure the safe, intact arrival of the contents of each package being shipped.
e. Provide appropriate packaging components (for example, wet ice, dry ice, or cold packs) to ensure the safe, intact arrival of clinical agents requiring maintenance of low temperatures.
f. Supply reusable, electronic monitoring devices for temperature and humidity monitoring during transit. Provide the software for downloading, reading and reviewing data from the electronic monitoring devices.
g. Provide the DMID-funded clinical research sites and DMID-approved testing laboratories with a cushioned mailer with a CASR return label and prepaid postage/courier label for returning the electronic monitoring devices.
h. Evaluate electronic monitoring device data to ensure that clinical agents have been shipped within product specifications. Notify the Project Officer and supplier of any shipping deviations within 24 hours of receipt of the returned electronic monitoring device. The Project Officer will determine if the clinical agent is acceptable for use.
i. Establish and maintain a database of all information downloaded from electronic monitoring devices. This information shall be maintained by protocol, clinical agent, lot number, Clinical Principal Investigator to whom clinical agent has been shipped, shipment date and clinical research site or testing laboratory. Information downloaded from the electronic monitoring devices shall be made available upon request either electronically as an Adobe PDF file or by fax to product manufacturers and to the Project Officer.
j. Deliver to the Project Officer samples, including product packaging containers, (e.g., bottles, vials, etc.), new clinical agents, monitoring devices, or supplies that have been identified as having problems. Samples shall be delivered to the Project Officer within 24 hours of identifying the problem. Under certain circumstances, the CASR may be requested to make same day deliveries of requested sample items.
k. At the request of the Project Officer, provide emergency shipments and carry out other functions after normal hours of operation. Shipments after normal working hours and on weekends should only be made in extreme circumstances such as in the case of a public health emergency or distribution of a clinical agent under emergency use IND. Except for emergency shipments and other emergency functions, the CASR is required to be open and accessible during the hours of 8:30 AM to 5:00 PM Eastern Standard/Daylight Time, Monday through Friday, except for official U.S. Federal holidays. In addition, the CASR shall be required to establish procedures for emergency closings due to weather conditions or other unexpected closings mandated by local, state and Federal government authorities and shall be required to remain open during emergency closings if necessary to support critical time-sensitive clinical research activities.

5. Documents and Regulations for Shipping Clinical Agents

Obtain and maintain all required permits and authorizations to comply with domestic and non-domestic laws and regulations for shipping and distribution of clinical agents.

a. Generate and obtain all required shipping documents, including: U.S. Department of Agriculture permits, FDA Investigational New Drug Application (IND) Number assignment, pro forma invoices, letters of donation, Material Transfer Agreements, Clinical Trial Agreements, Clinical Materials Supply Agreements, CoAs, commercial invoices, Material Safety Data Sheets (MSDS) and Certificates of Pharmaceutical Product.
b. Research the regulations and documents required for shipment of clinical agents to non-domestic countries, and develop and maintain a database of this information for all countries with DMID-funded clinical research sites. This database shall be regularly updated and information shall be provided to the Project Officer and other DMID staff upon request.
c. Ensure that all required import and export permits have been received from non-domestic DMID-funded clinical research sites, the broker retained by the DMID-funded clinical research sites, the embassies of those countries, and the customs offices or other pertinent offices of those countries, prior to processing shipments. All import and export documents must be maintained on file at the CASR for the life of the contract.
d. Ensure that the chosen courier service has experience and expertise in non-domestic shipments of clinical agents. Collaborate with the courier service in providing assistance to non-domestic clinical research sites for obtaining necessary import, export, customs and tax exemption documents.
e. Possess and maintain appropriate licenses and permits required by local, state, province, domestic, and non-domestic, country-specific government authorities for the safe import, storage, handling, transportation, and distribution of drugs, biologics, controlled substances and devices. Process any document requiring embassy approval through the appropriate embassy. Obtain the appropriate interstate, intrastate and non-domestic import/export shipping licenses and permits for transporting drugs, biologics, controlled substances, and devices.

6. Tracking and Inventory Management of Clinical Agents

Provide tracking and inventory management of clinical agents as follows:

a. Track, code, and archive information on all clinical agents received, acquired, stored and shipped to and from the CASR. For each clinical agent, provide the following information into an electronic inventory management system:

    i. Identity of clinical agent
    ii. Manufacturer/source of clinical agent
    iii. Source contact
    iv. Quantity received
    v. Storage location
    vi. Quantity shipped
    vii. Shipping request

viii. DMID-funded clinical research site or DMID-approved testing laboratory
ix. Protocol number
x. Expiration and retest dates

Additional elements to be tracked and coded will be discussed with and approved by the Project Officer.

b. Monitor monthly clinical agent use rate and notify the Project Officer of low inventories, upcoming expiration or retest dates and unusual increases or decreases in amount shipped to DMID-funded clinical research sites and DMID-approved testing laboratories.
c. Perform a physical inventory of all clinical agents held at the CASR at least annually, or more frequently when requested by the Project Officer. In addition, conduct protocol-specific inventories as requested by the Project Officer. Notify the Project Officer of any discrepancies that cannot be reconciled with the current computerized inventory.
d. Provide a monthly summary of inventory activity to be included in the Monthly Progress Reports to the Project Officer. The summary shall include the following information:

i. number of shipments received;
ii. amount of clinical agent distributed;
iii. number of recalled and expired clinical agents;
iv. number of new clinical agents received; and
v. number of clinical agents disposed.

e. Contact product manufacturers for breaks in cold chain to determine acceptability for future use and if needed, provide written recommendations to the Project Officer on the continued use of product.

7. Quarantine and Final Disposition of Clinical Agents

Upon written approval from the Project Officer, quarantine and dispose of unused, expired, and/or recalled clinical agents, either returned to the CASR from DMID-funded clinical research sites, or removed from active stock at the CASR in accordance with 21 CFR 211.204.

a. Provide quarantine space for all returned and expired clinical agents at the appropriate storage condition temperatures (i.e.,-80°C, -20°C, 2°C to 8°C, controlled room temperature, USP).
b. Establish an onsite final disposition program that meets all U.S. and local public and occupational health, safety and environmental protection regulations. Provide a draft Onsite Disposition Plan to the Project Officer for review and approval within 30 business days of the effective date of the contract. Revise the Plan in accordance with Project Officer comments and submit a final Onsite Disposition Plan within 10 business days of receipt of Project Officer comments.
c. Remove active stock at the CASR to quarantine when clinical agents have been recalled or are no longer to be shipped to DMID-funded clinical research sites.
d. Provide written notification to the Project Officer within 2 business days of when the CASR becomes aware that clinical agents are to be returned to the CASR for any of the following reasons:

i. a clinical agent lot number is recalled by the manufacturer;
ii. study treatment using the product has ended;
iii. clinical agent has reached the expiration date;
iv. the cold chain requirements were breached; and/or
v. clinical agent has reached the useful shelf life limit.

Include in the notification, the lot numbers and a complete list of protocols using that lot of clinical agent. Ensure that the Monthly Progress Reports include all such notifications.

e. Provide, in writing, all applicable special handling instructions (i.e., in the case of dangerous goods) to DMID-funded clinical research sites for the return of clinical agents to the CASR.
f. Receive recalled, expired or unused clinical agents returned from DMID-funded clinical research sites. Process returns in compliance with local, state and U.S. regulations.
g. Quarantine all returned and expired products from other inventory at the CASR.
h. Perform end-of-study reconciliation of CASR accountability records, reconciling clinical agents shipped with those used, returned, or destroyed. Obtain and maintain documentation of the final clinical agent disposition from all DMID-funded clinical research sites. Submit a Final Study Disposition Report to the Project Officer for the regulatory records within 5 business days of close out of a study.
i. Upon written approval of the Project Officer, dispose of returned clinical agents in accordance with local, state, and U.S. regulations. This may require destruction of the clinical agent, return of the clinical agent to the manufacturer, or relabeling of the clinical agent for other purposes.
j. Provide the Project Officer with a list of clinical agents that are no longer stored under an active protocol as part of the Monthly Progress Reports for disposition determination.

8. Acquisition of Clinical Agents

At the request of the Project Officer, acquire clinical agents required for the implementation of DMID-funded clinical trials, and perform non-clinical testing on the acquired clinical agents as follows:

a. Acquire clinical agents manufactured in compliance with cGMP regulations from product manufacturers approved by the Project Officer. The acquisition shall include clinical agents at all stages of development, such as:

i. Pilot lot material;
ii. Bulk substance;
iii. Master and working cell banks; and
iv. Final drug product.

b. Carry out all necessary testing of acquired clinical agents as outlined in Federal Regulations 21CFR610 and 21CFR211 and as requested by the Project Officer.

c. Provide for additional *in vitro* and *in vivo* safety testing of acquired clinical agents as required on a case-by-case product-specific basis, such as demonstration of freedom from adventitious agents and demonstration of product attenuation.
d. Within 10 business days of completion of non-clinical testing, prepare and submit to the Project Officer for review and approval final Non-Clinical Study Reports.

B. CLINICAL SPECIMENS

1. Receipt and Short Term Storage of Clinical Specimens from DMID-Funded Clinical Research Sites

Receive clinical specimens from DMID-funded clinical research sites and provide short-term storage (up to 2 years) of clinical specimens in support of DMID-funded clinical research through carrying out the following functions:

a. Develop, following specifications provided by the Project Officer, a clinical specimen shipping request form for the Project Officer use in reviewing and approving requests from DMID-funded clinical research sites to ship clinical specimens to the CASR. Provide a draft shipping request form to the Project Officer for review and approval within 5 business days from the effective date of the contract. The Project Officer will provide comments within 3 business days of receipt of the form. Revise the form in accordance with Project Officer comments, and submit the final shipping request form to the Project Officer within 5 business days of receipt of Project Officer comments.
b. Upon receipt of the Project Officer-approved clinical specimen shipping request to provide short-term storage of clinical specimens, the Contractor shall arrange and coordinate with the DMID-funded clinical research sites, shipment of the clinical specimens to the CASR. Provide written instructions for shipping and handling of clinical specimens to DMID-funded clinical research sites to preserve specimen integrity and utility. Instructions shall include proper labeling, storage and shipping requirements and shall be compliant with all domestic and non-domestic laws and regulations for shipping and handling of clinical specimens.
c. Receive shipments of clinical specimens from domestic and non-domestic DMID-funded clinical research sites. Clinical specimen shipments from domestic sites shall be received by overnight express shipment, and clinical specimen shipments from non-domestic sites shall be received within 3-5 calendar days based on the country.
d. Perform inspection and verification of all incoming shipments at the vial level. Reconcile with shipping lists and confirm identification of clinical specimens, note and document conditions of receipt, inspect for correct labeling, and notify the Project Officer of any discrepancies or problems within 24 hours of receipt.
e. Notify DMID-funded clinical research sites within 24 hours of shipment receipt, of all discrepancies found for each shipment. Obtain and verify corrective actions received from clinical research sites within 3 business days of electronic receipt of the corrective action.
f. Track and record contents and condition of the shipments. Electronically document chain of custody, shipment receipt date, condition and inspection of specimens and shipments, storage and monitoring of clinical specimens from DMID-funded clinical research sites. Provide a summary report of shipments received in the Monthly Progress Reports.

g. Store/monitor specimens as indicated by the investigator or as directed by the Project Officer.
h. Provide storage facilities to accommodate the following specifications for clinical specimens:

- -80°C, (approximately 400 cu. ft.)
- -20°C, (approximately 400 cu. ft.)

2. Aliquoting and Labeling of Clinical Specimens

Aliquot and label clinical specimens received from DMID-funded clinical research sites through carrying out the following functions:

a. Provide and maintain the necessary clean room(s) and equipment for the aliquoting and labeling of clinical specimens.
b. Upon receipt of written request from the Project Officer, aliquot and label clinical specimens for distribution in appropriate containers.
c. Track aliquoting and labeling activities and provide reports of such activities to the Project Officer in the Monthly Progress Reports.

3. Shipping and Distribution of Clinical Specimens

Ship clinical specimens to DMID-approved testing laboratories at the request of the Project Officer in accordance with GLP and GCP regulations and in compliance with domestic and non-domestic laws and regulations:

a. Provide shipping cartons, cushioning materials, labels, sealing tape, insulation materials, and all other supplies to ensure the safe, intact arrival of the contents of each package being shipped.
b. Use shipping containers that comply with current domestic and non-domestic transport regulations and pertinent International Air Transport Association (http://www.iata.org/dgr.htm) and International Civil Aviation Organization (http://www.icao.int/) regulations concerning dangerous goods.
c. Provide appropriate packaging components (for example, wet ice, dry ice, or cold packs) to ensure the safe, intact arrival of clinical specimens requiring maintenance of low temperatures.
d. Develop, following specifications provided by the Project Officer, a clinical specimen receipt form to be sent to the DMID-approved testing laboratory for the verification of shipment receipt. Provide a draft clinical specimen receipt form to the Project Officer for review and approval within 5 business days from the effective date of the contract. The Project Officer will provide comments within 3 business days of receipt of the form. Revise the form in accordance with Project Officer comments, and submit final clinical specimen receipt forms to the Project Officer within 5 business days of receipt of Project Officer comments. This form shall be enclosed in all clinical specimen shipments and shall be returned to the Contractor to confirm receipt and condition of clinical specimen.
e. Ship clinical specimens to DMID-approved testing laboratories so that domestic shipments are received within 24 hours and non-domestic shipments are received within 3-5 calendar days.

4. Tracking and Inventory Management of Clinical Specimens

Track and provide inventory management of clinical specimens as follows:

a. Track, code, and archive information on all clinical specimens received, stored, and shipped to and from the CASR. For each batch of clinical specimens, provide the following elements into an electronic inventory management system:

   i. Protocol number;
   ii. Specimen identification number;
   iii. Origination site;
   iv. DMID program;
   v. Date of receipt;
   vi. Number of units received;
   vii. Number of aliquoted units made;
   viii. Total number of units;
   ix. Storage location within the CASR;
   x. Identity and destination of shipping requests; and
   xi. Number of units shipped to each destination.

   Additional elements to be tracked and coded will be discussed with and approved by the Project Officer.

b. Perform a physical inventory of clinical specimens at least annually, or more frequently when requested by the Project Officer. Notify the Project Officer of any discrepancies that cannot be reconciled with the current computerized inventory. Correct any discrepancies identified and provide an Inventory Report to the Project Officer within 10 business days of completing the physical inventory, including discrepancies and corrective and preventative actions taken.
c. Provide a summary of monthly inventory activity to the Project Officer in the Monthly Project Reports. Include the following information:

   i. number of clinical specimen shipments received;
   ii. number of clinical specimen shipped and distributed; and
   iii. number of clinical specimens disposed.

5. Final Disposition of Clinical Specimens

a. Within 30 business days of the two-year storage expiration date for clinical specimens at the CASR, provide e-mail notification to the Project Officer for approval to dispose.
b. Upon written approval from the Project Officer, remove expired clinical specimens from active stock at the CASR and dispose in accordance with local, state, and U.S. regulations.

C. OVERALL CONTRACT REQUIREMENTS

1. Security, Safety, Monitoring and Maintenance of Facilities and Equipment

Provide safe, secure, monitored, and maintained facilities and equipment for the receipt, storage, quarantine, processing and distribution of clinical agents and clinical

specimens that are compliant with cGMP, GLP and GCP and have the capacity to perform the following:

a. Provide protective garments, equipment and monitoring to assure safe handling of potentially infectious and hazardous microorganisms for all personnel involved.
b. Where applicable, ensure the conduct of work in accordance with DHHS regulations regarding the transfer of Select Agents (U.S. Code of Federal Regulations 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121 (http://www.cdc.gov/od/sap/index.htm)).
c. Provide safe, biocontainment facilities and staff with the required level of training, experience and expertise to operate the facilities and conduct work in accordance with the Biosafety in Microbiology and Biomedical Laboratories (BMBL) Guidelines (http://bmbl.od.nih.gov/).
d. Provide up-to-date, 24-hour a day, 7 days a week, monitored and alarmed, electronic security systems with real time notification to the Contractor or designee to prevent theft, misuse or damage to clinical agents and clinical specimens stored at the CASR.
e. Provide an electronic 24-hour a day, 7 days a week, temperature monitoring system to record and ensure the maintenance of appropriate storage temperature for the clinical agents and clinical specimens (controlled room temperature, refrigerators, freezers). If a failure to the primary system should occur, the monitoring system or service must continue to attempt to reach the Contractor or designee until such contact has been made. The Project Officer shall be notified within 24 hours of temperature failure. All temperature records must be maintained for the life of the contract.
f. Provide complete back-up equipment for maintaining storage conditions for both clinical agents and clinical specimens at: -194°C, -80°C, -20°C, or 2°C to 8°C.
g. Provide electric power generators with transfer switches between the electric utility and the power generator to insure automatic, safe, continuous and reliable source of power in the event of failure of electricity supplies.
h. Provide a system to detect variances outside of the specified range such as cold storage, controlled room temperature, USP-specified conditions, and humidity controlled areas.
i. Provide a clean agent fire suppression system that is environmentally acceptable and leaves no residues.
j. Provide temperature, humidity, light and environment controlled and monitored conditions for clinical agents sensitive to low or high humidity, carbon dioxide or light.
k. Develop and implement, when necessary, a plan for the transfer of clinical agents and clinical specimens to appropriate storage conditions in the event of power failure, fire, flood, or other occurrences capable of damaging clinical agents or clinical specimens. Provide a draft plan to the Project Officer for review and approval within 30 business days of the effective date of the contract. Revise the draft plan in accordance with Project Officer comments, and submit the final plan to the Project Officer within 5 business days of receipt of Project Officer comments.

2. Electronic Information Systems, Data Management, and System Security

a. <u>CASR Database Management System</u>

i. Implement, maintain and operate the existing DMID database system, CARIM. Within 30 business days of the effective date of the contract, establish a link to HSROAD to obtain regulatory information needed for shipment of clinical agents. Ensure adequate technical support and equipment to maintain the following system features:

1) Archiving, tracking, and coding all clinical agents and clinical specimens received and stored at the CASR.

2) Archiving, tracking, and coding all requests for clinical agents and clinical specimens to be shipped from the CASR to DMID-funded clinical sites and DMID-approved testing laboratories.

3) Generation of integrated reports to sort data by:

Clinical Agents

- Identity of clinical agent
- Lot number
- Manufacturer
- Source Contact
- Strength, unit, and formulation
- Quantity received
- Quantity shipped
- Expiration and retest dates
- DMID-funded clinical research site
- Protocol number
- DMID Program
- DMID Regulatory Affairs Specialist assignment
- Shipping request
- Clinical agents returned
- Clinical agents quarantined
- Site distribution of clinical agents
- Inventory of clinical agents

Clinical specimens

- Identity of clinical specimen
- Protocol number
- DMID-funded clinical research site of origin
- DMID Program
- DMID-approved testing laboratory
- Source contact
- Inventory of clinical specimens

Additional fields will be discussed with and approved by the Project Officer.

4) An operational back-up system to ensure that archived materials are protected and preserved in the event of power failure, fire, flooding, or other catastrophic event.

5) Compatibility with information systems used by DMID and DMID clinical research support contractors to ensure accessibility of data, including DMID-supplied software components or eXtensible Markup Language (XML) schemas in applications, where needed, to affect specific types of transactions, Graphical User Interface (GUI), and other software-based tasks that interact with DMID-owned databases.

ii. Implement, maintain, and operate an electronic ordering system to be used by DMID-supported investigators and staff to request shipping of clinical agents and clinical specimens from the CASR to DMID-approved clinical research sites and DMID-approved testing laboratories.

iii. Provide programming and IT user support for the CARIM including:

1) Staff to establish, maintain, operate and enhance existing and new functions and modules for the CARIM; ensure that the system is Part 11 compliant (21 CFR 11).
2) Development and implementation of on-going training in the use of the CARIM for DMID staff and other individuals approved by the Project Officer, such as clinical investigators.

iv. Investigate new and improved technologies to enhance the efficiency and ease of use of CARIM. Within 60 business days of the effective date of the contract, provide an assessment and written recommendations to the Project Officer for modifications and improvements to CARIM, including a breakdown of the costs associated with all recommended modifications and improvements. Upon receipt of written approval from the Project Officer, implement system modifications and improvements within the timeline specified by the Project Officer depending upon the extent of the approved modifications and improvements. All plans for any software development shall be submitted to the Project Officer and the Contracting Officer for review and approval prior to implementation.

b. <u>Data Management</u>

i. Ensure the capacity of the CASR database systems to access, receive, transmit, upload and download specific data from other DMID-owned data management systems. This includes compatibility with multiple and varied hardware and software systems to receive, scan and transmit electronic messages, documents, data files, query forms and reports to/from DMID, the Contractor and other DMID clinical research support contractors.

ii. Ensure the effective and efficient coordination of data to complete specified functions in collaboration with the DMID Regulatory Affairs Support contractor, the DMID Clinical Trials Management (CTM) Support contractor, and the DMID Statistical and Data Coordinating Center (SDCC) contractor. These functions include:

1) *Receipt and storage of clinical agents requiring Investigational New Drug (IND) and Investigational Device Exemption (IDE) Applications:* Track and obtain regulatory information from the DMID-owned

Regulatory Affairs Support Database, HSROAD to verify regulatory status information for each DMID IND or IDE and to determine if the IND or IDE is effective and there are no clinical hold issues, prior to receipt of clinical agent from supplier.

2) *Distribution of clinical agents under INDs and IDEs*: Track and obtain regulatory information, from HSROAD to verify that DMID-funded clinical research sites have submitted all essential regulatory documents required for receiving clinical agents from the CASR and the sites have been approved to initiate clinical protocols, prior to shipping clinical agent to the DMID-funded clinical research sites.
3) *Receipt, storage, and distribution of clinical specimens from the CASR to DMID approved testing laboratories:* Utilize software to be provided by the SDCC contractor to barcode, scan, identify and track clinical specimens obtained from DMID-funded clinical research sites, prior to receiving or shipping clinical specimens.

iii. Develop and implement validation processes and procedures to ensure the accuracy, completeness and integrity of data in the CARIM Database System. Within 30 business days of the effective date of the contract, submit a Draft Data Validation Plan for validation processes and procedures for review by the Project Officer. Modify the Plan in accordance with Project Officer's comments, and submit the Final Data Validation Plan within 10 business days of receipt of Project Officer comments.

iv. As part of the Monthly Progress Reports, provide information on data integrity, completeness and accuracy, including identification of errors and problems, recommendations for correcting errors and resolving problems, and the implementation of corrective actions approved by the Project Officer.

c. <u>System Security</u>

Develop and implement an Information Security Plan which meets NIH Information Security requirements and complies with the Automated Information Systems Security Program of DHHS (http://www.hhs.gov/ocio/policy/index.html#Security). Within 20 business days of the effective date of the contract, submit, for Project Officer review and approval, an Information Security Plan. References for system security information and guidance are located in Section H of the contract at the end of the Article entitled "Information Security." Requirements for information security include the following:

i. A System's Security Plan (SSP), which minimally shall include the Risk Analysis (RA) and the Continuity of Operations Plan (COOP – also known as the Contingency Plan).
ii. The preparation and submission of an annual Information System Security Plan (ISSP), following the instructions in the HHS SecureOne Policy (http://www.hhs.gov/ocio/policy/index.html#Security) for review and approval by the Project Officer and the NIAID Information System Security Officer (ISSO).
iii. A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and

controls, and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to the NIH/DHHS for its own system's security reporting requirements.

iv. The preparation and submission, for Project Officer approval, of a RA following the guidance given in the HHS SecureOne Policy. The RA is to be maintained and updated every 3 years, or in advance of implementing major system modifications or enhancements.

v. The development and maintenance of an up-to-date COOP following the guidance in the HHS SecureOne Policy. At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every 6 months.

vi. Plans, procedures and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data. This includes data integrity and security during electronic transmission or during transit.

3. Internal Training of CASR Personnel

a. Provide and document completion of training for CASR personnel regarding safety measures for handling clinical agents and clinical specimens; maintaining cold chain measures; receipt, storage, and shipping procedures; inventory procedures; labeling/randomization procedures; and final disposition of clinical agents and clinical specimens.

b. Provide and document completion of annual training of CASR personnel for facility security, fire drills, fire suppression system, cGMP, dry ice handling, use of personal protection and protection equipment, employee-monitoring-systems for use in walk-in freezers, and chemical spill clean-up procedures for all personnel with access to the CASR.

c. Provide and document completion of training for CASR personnel in the proper packing and use of validated shipping containers, on the use of standard forms and templates for letters and memoranda, and record keeping practices.

d. Review new SOPs with applicable staff and document by signature to verify that the review has occurred.

e. Provide and document completion of training to CASR personnel in the use of computer systems for databases and software systems required to meet the objectives and functions of the CASR.

f. Establish a forum such as weekly staff meetings, to ensure that CASR personnel are informed and have the opportunity to:

i. Review new and revised SOPs;
ii. Obtain training on new and revised SOPs;
iii. Review established SOPs when breaches in procedures have occurred;
iv. Identify protocol-specific issues;
v. Cross-train employees for prevention of impeded work flow;
vi. Brief staff on current issues; and
vii. Identify issues that need to be brought to the attention of the Project Officer.

4. Quality Assurance/ Quality Control (QA/QC)

a. Quality Assurance/Quality Control Plan

i. Develop and implement a Quality Assurance/Quality Control Plan to standardize contract processes to ensure that the conduct of all CASR activities complies with GCP, GLP and cGMP regulations and meets the requirements of the contract. Specifically, develop and implement a QA/QC Plan for the following tasks:

1) Provide a list of SOPs for all operations outlined in the Statement of Work within 30 business days of the effective date of the contract and ensure that copies of SOPs are available for review by the Project Officer upon request.
2) Establish SOPs to meet the requirements of this Statement of Work within 60 business days of contract award. Submit modifications to existing SOPs arising during the contract period of performance to the Project Officer for review and approval prior to implementation.
3) Maintain version control of all SOPs (both QA and technical) to ensure that the current SOP versions are utilized and superseded versions are removed from circulation.
4) Review and approve all SOPs prior to distribution and use.
5) Ensure that all CASR personnel are trained on the implementation of approved SOPs prior to use and document that all such training has been completed. Ensure the conduct and document the completion of annual training for all CASR personnel regarding biosafety procedures, QA procedures, and SOPs for the conduct of activities outlined in the Statement of Work.
6) Maintain a list of facility accreditations, a record of facility maintenance, and a list of the validation status of facilities, equipment, and computer software.
7) Ensure and document that laboratory equipment, including power supplies, freezers, refrigerators, and alarms, is suitably qualified, calibrated and maintained.
8) Ensure and document adherence to all applicable GLP, cGMP, and GCP requirements and guidelines by the Contractor and any subcontractors.
9) Ensure and document safety and security of facilities and equipment
10) Ensure that all data are recorded daily, all original (unaltered) records are retained, signed, and dated by the repository personnel directly conducting the CASR activities, and all records meet good record keeping standards.
11) Develop and implement a record retention and storage plan.
12) Ensure the accuracy and integrity of tracking for all CASR activities.

ii. Within 15 business days of the effective date of the contract, submit a Draft QA/QC Plan for Project Officer review and approval. Include a description of the proposed systems to track and document activities described in the SOW and ensure quality assurance (QA) throughout the process. The Project

Officer will provide comments on the Draft QA/QC Plan within 14 business days of receipt. Submit the Final QA/QC Plan, which addresses Project Officer comments 10 business days after receipt of Project Officer comments. The QA/QC Plan shall include SOPs for establishing and maintaining the QA/QC processes and approaches/methods to document, identify the source(s) for, and address problems and deviations as they occur, as well as recommendations for the resolution of problems and correction of deviations. Any proposed modifications to the QA/QC Plan, including SOPs, shall be submitted to the Project Officer for review and approval prior to implementation.

b. Site Visits and Audits

Arrange for site visits and independent audits of Contractor and subcontractor facilities as needed or as requested by the Project Officer, to evaluate compliance with domestic and non-domestic laws and regulations and FDA regulations and guidances, including those required to meet GLP, cGMP, and GCP standards, DMID policies, and the terms of the contract.

i. Ensure that appropriate Contractor and/or subcontractor staff and all necessary records are available for site visits or audits.

ii. Provide interim and final audit reports to the Project Officer and the Contracting Officer within 20 business days of the completion of the audit or site visit.

5. Project Management

a. Overall Project Management

i. Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out in collaboration with other DMID contractors and the management of functions and activities carried out by any subcontractors.

ii. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, management and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.

iii. Designate a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.

iv. Provide personnel to coordinate contract specific activities and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and subcontractors.

b. Meetings

i. *Contract Initiation Meeting*

Within 10 business days of the effective date of the contract, the Principal Investigator (PI) and other key personnel, as recommended by the PI and approved by the Project Officer, shall participate in a one-day contract initiation meeting with the Project Officer, the Contracting Officer, and other key DMID staff, to be held in the Bethesda, Maryland area. The purpose of this contract initiation meeting is to orient the Contractor and subcontractors to NIAID contract procedures, review the scientific and QA approaches to be employed during the contract period, and address issues, questions, processes and timelines for the initiation of contract activities. The Contractor shall prepare and submit a meeting summary to the Project Officer and meeting participants within 3 business days after the contract Initiation meeting.

ii. *Weekly Progress Meetings/Teleconferences*

The PI, key Contractor personnel and, when appropriate, senior subcontractor staff, as designated by the PI, shall participate in weekly meetings and/or teleconferences with the Project Officer and other relevant DMID staff to discuss the status of ongoing activities, identify and develop approaches to resolving problems encountered with respect to clinical agent and clinical specimen repository responsibilities, and review plans for upcoming activities. The Contractor shall prepare and submit meeting agendas and background materials to the Project Officer for review and approval no less than 2 business days in advance of the meeting or teleconference, distribute meeting materials to meeting or teleconference participants within 1 business day in advance of the meeting or teleconference, and prepare and submit meeting summaries to the Project Officer and participants within 2 business days after each meeting or teleconference.

iii. *Annual Meetings*

The PI, key Contractor personnel and, when appropriate, senior subcontractor staff, as designated by the PI, shall participate in annual two (2) day meetings, to be held in the Bethesda, Maryland area, for the purposes of future planning and evaluation of ongoing activities. These meetings shall be convened at the request of the Project Officer and shall include other DMID staff as deemed necessary by the Project Officer. The Contractor shall be responsible for preparing and providing meeting agendas and background information to the Project Officer 10 business days in advance of the meetings. The Contractor shall also prepare meeting summaries and distribute to all participants within 5 business days of the conclusion of meeting.

iv. *Other Meetings/Teleconferences*

The PI, key Contractor personnel and, where appropriate, senior subcontractor staff, as designated by the PI, shall participate in other meetings and/or teleconferences, including DMID-funded clinical investigator meetings and Annual Meetings of the DMID-funded Clinical Research Networks as requested by the Project Officer, to present information and answer questions regarding clinical agent requests, clinical agent handling, shipping and receipt of clinical agents and specimens. The Contractor shall be responsible for preparing presentation material to the Project Officer for approval 5 days prior to the meeting.

6. Initial and Final Transition

a. Initial Transition

i. In the event of contract award to a new contractor, provide for the efficient, orderly and safe transition of contract activities, data systems, documents and other information from the incumbent contractor to ensure a seamless transition without loss of time, compromise of clinical agents and clinical specimens or interruption to the conduct of ongoing DMID-funded clinical research or clinical research in development. The following shall be transferred to the Contractor:

Clinical Agents:

1) Clinical agents;
2) Inventory and storage records;
3) Files of all product related correspondence;
4) Shipping and receiving records;
5) Databases, software systems, including the CARIM Database System;
6) Government-furnished property;
7) Shipping materials, cartons and labels;
8) Validated shipping procedures;
9) DMID agreements related to clinical agents, i.e. Material Transfer Agreements and Clinical Material Supply Agreements between DMID and the testing laboratory or product manufacturer; and
10) Clinical agent-related documents.

Clinical Specimens:

1) Clinical specimens;
2) Inventory and storage records;
3) Files of all correspondence related to the DMID-funded clinical research sites from which clinical specimens are obtained;
4) Shipping and receiving records;
5) Validated shipping procedures;
6) DMID agreements related to clinical specimens, i.e. Clinical Trial Agreements between DMID and the product manufacturer; and
7) Clinical specimen-related documents, i.e., shipment records listing specimens.

ii. *Draft Initial Transition Plan*: Within 5 business days of the contract effective date, the Project Officer will provide to the Contractor a copy of the Final Transition Plan from the incumbent contractor. Based on this Final Transition Plan and the requirements set forth in the Statement of Work, the Contractor shall develop and submit within 15 business days of the effective date of the contract, for Project Officer review and approval, a Draft Initial Transition Plan specifying proposed timelines and milestones to ensure an efficient, safe and orderly transition of contract data, systems and activities, including the installation of the CARIM database, as well as the staff to be assigned to implement the initial transition with defined roles and responsibilities.

iii. *Final Initial Transition Plan*: Revise the Draft Initial Transition Plan as necessary to address Project Officer comments and submit the Final Initial Transition Plan within 10 business days of receipt of Project Officer comments.

iv. Provide training for all Contractor staff associated with the transfer and assumption of contract activities.

v. Implement the approved Final Initial Transition Plan, as approved by the Project Officer, including all tasks that are associated with the relocation effort from the incumbent contractor. This effort shall also entail a complete physical inventory of clinical agents and clinical specimens, which should be completed within 30 days of contract award. The Initial Transition shall be completed within 60 business days of the effective date of the contract, and the Contractor shall submit to the Project Officer an Initial Transition Report summarizing all transition activities within 30 business days of Initial Transition completion.

b. Final Transition

i. In the event of contract award to a new contractor, provide for the efficient, orderly and safe transition of contract activities, data systems, documents and other information to the successor contractor or to the Government, without loss of time or interruption to the conduct of ongoing DMID-supported clinical research or clinical research in development. The following will be transferred by the Contractor:

Clinical Agents:

1) Clinical agents;
2) Inventory and storage records;
3) Files of all product related correspondence;
4) Shipping and receiving records;
5) Databases and software systems;
6) Government-furnished property;
7) Shipping materials, cartons and labels;
8) DMID agreements related to clinical agents; and
9) Clinical agent-related documents.

Clinical Specimens:

1) Clinical specimens;

2) Inventory and storage records;
3) Files of all correspondence related to the DMID-funded clinical research sites from which clinical specimens are obtained;
4) Shipping and receiving records;
5) DMID agreements related to clinical specimens; and
6) Clinical specimen-related documents.

All software, Operating System (OS) languages, source code, tools, and documentation developed as part of the contract, and any Commercial-off-the-shelf (COTS) products purchased under the contract shall be transferred to the new contractor or DMID and must be removed from all Contractor-owned equipment. Management tools, computer systems, databases, source code, validation data, and any other electronic files or items developed under this contract shall remain the property of the Government.

ii. *Draft Final Transition Plan:* One year prior to the completion date of the contract, submit for Project Officer review and approval, a Draft Final Transition Plan specifying proposed timelines to ensure an efficient, safe and orderly transition of contract data, systems and activities, as well as the staff to be assigned to implement the Final Transition with defined roles and responsibilities. This includes removal of all government information from electronic systems maintained by the Contractor.

iii. *Final Transition Plan:* Revise the Draft Final Transition Plan as necessary to address Project Officer comments and submit the Final Transition Plan 10 months prior to the completion date of the contract.

iv. Implement the approved Final Transition Plan, as approved by the Project Officer, including all tasks associated with the relocation effort to the new contractor or transfer to the Government. The Final Transition shall be completed within 45 business days of the completion date of the contract, and the Contractor shall submit to the Project Officer a Final Transition Report summarizing all transition activities 20 business days prior to the completion date of the contract.

D. OPTIONS

In addition to the services outlined above to be provided for the basic requirement, Options for additional services under the contract may be exercised at the discretion of the Government and are defined as follows:

Option 1: The Contractor shall increase clinical specimen capacity of the CASR in order to accommodate the following:

- -80^{o}C (approximately 1600 cu. ft.)

- -20^{o}C (approximately 1600 cu. ft.)

Option 2: The Contractor shall increase the length of time for the storage of clinical specimens in the CASR to exceed the short-term storage requirement of two (2) years as specified in the base requirement, to provide for storage until the end of the contract period of performance.

Option 3: The Government may extend the contract for up to an additional two (2) years beyond the contract base period of performance. If this option is exercised, the services required under this option shall be of the same scope provided for in the basic requirement, as well as what is provided for in Options 1 and 2, should these two options be exercised by the Government.

Under each Option, the Contractor shall provide the following:

1. OPTION PLAN DEVELOPMENT:
   The Contractor shall develop and provide to the Project Officer within 30 calendar days of proposed exercise of an option, a plan for the provision of the services, including all associated personnel, facilities, equipment and other resources, necessary to implement the option, and a timeline and budget for initiation, implementation, management, and completion of all tasks.
2. OPTION PLAN IMPLEMENTATION:
   Based on the Project Officer's recommendation to implement the Option Plan, the Contracting Officer will authorize the exercise of each Option through a Modification to the contract. The Contractor shall begin implementation of options within 40 business days of receipt of the contract Modification.

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND FORMAT FOR TECHNICAL PROPOSAL

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a table of contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire Technical Proposal is **200** pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review. Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

1) PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
2) PROJECT OBJECTIVES, NIH FORM 1688
3) GOVERNMENT NOTICE FOR HANDLING PROPOSALS
4) PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
5) TABLE OF CONTENTS
6) MANDATORY QUALIFICATION CRITERIA

The Mandatory Qualification Criteria (MQC), identified in SECTION M of this solicitation, must be met at the time of receipt of the Original Proposal submission.

Documentation to support compliance with the MQC must be provided for the offeror and any proposed subcontractor(s). Include all information relevant to the MQC in this

clearly marked section of your Technical Proposal. Include copies of all materials necessary to demonstrate that you have met the MQC.

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3- page maximum)

Provide a brief description of the proposed project, including:

1) A description of the activities to be performed by the offeror and those that shall be provided by any proposed subcontractor, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.
2) A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.

SECTION 3: TECHNICAL APPROACH

A. Clinical Agents

1. Receipt and Storage of Clinical Agents (SOW A.1)

Describe proposed plans and procedures for the receipt and storage of clinical agents for use in DMID-sponsored clinical research. Include a discussion of the plans and procedures proposed to perform the following activities:

a. Verifying regulatory status of each clinical agent and arranging clinical agent shipments with the product suppliers.
b. Receiving clinical agents from a variety of sources, inspecting their condition, labeling, and packaging of the clinical agents, and reconciling shipment discrepancies.
c. Reviewing CoAs and other product information documentation for completeness and accuracy.
d. Storing clinical agents at temperatures and conditions specified by the manufacturer.
e. Ensuring continuous monitoring and documentation of clinical agent storage temperatures and content conditions.
f. Receiving and processing of shipments from domestic and non-domestic suppliers.

Identify potential problems associated with the receipt and storage of clinical agents and proposed solutions to overcome such problems. Describe the class (i.e., vaccine, therapeutic), type (i.e., drug, device), regulatory status, volume and source, including domestic or non-domestic suppliers, of clinical agents received and stored over the past 5 years. Describe the types of clinical studies and clinical testing for which the clinical agents were used.

2. Labeling, Packaging and Repackaging of Clinical Agents (SOW A.2)

Describe proposed plans and procedures to label, package, and repackage clinical agents for distribution to clinical research sites in accordance with clinical

research site-specific requirements. Include a discussion of the plans and procedures proposed for performing the following activities:

a. Repackaging clinical agents into a variety of packaging types, including subject-specific packaging and kits in accordance with randomization schemes provided.
b. Generating labels and affixing primary or auxiliary labels on 10,000 units per year.

Provide examples of the clinical agent labeling, packaging and repackaging activities over the past 5 years. Include a discussion of the problems encountered and the strategies used to resolve these problems.

3. Shipping Preparation Procedures and Equipment for Clinical Agents (SOW A.3)

Describe proposed approaches to ensure the adequacy of clinical agent packaging and shipping procedures and equipment, including:

a. Validation testing for cold chain shipping containers.
b. Validation testing for conditions required for controlled substances.
c. Preparing SOPs based on the results of validation testing.
d. Preparing shipments of clinical agents for both domestic and non-domestic DMID-funded clinical research sites.

Describe shipping preparation validation tests conducted within the past 5 years; summarize the results of the validation testing; and list the SOPs developed based on the results of the validation testing.

4. Shipping and Distribution of Clinical Agents (SOW A.4)

Describe proposed plans and procedures for shipping and distributing clinical agents to DMID-funded clinical research sites and DMID-approved testing laboratories. Describe existing procedures/approaches to ensure compliance with FDA, domestic and non-domestic regulations for the shipping and distribution of investigational and commercial clinical agents. Include a discussion of the plans and procedures proposed for performing the following activities:

a. Selecting freight forwarders, couriers, and customs brokers to meet the needs of the clinical agent based on destination, protection required for the clinical agents, and performance history.
b. Verifying and processing clinical agent requests and filling orders correctly.
c. Ensuring that shipments of clinical agents are routinely received at domestic sites within 24 hours and at non-domestic sites within 3-5 calendar days.
d. Shipping under conditions compatible with clinical agent storage requirements, domestically and non-domestically.
e. Using appropriate types and quantities of packaging components to ensure the safe, intact arrival of clinical agents.
f. Monitoring clinical agent shipments with reusable electronic monitoring devices.

Provide a list of domestic and non-domestic clinical research sites and approved testing laboratories to which clinical agents were distributed over the past 5 years. Describe the types of requests for clinical agents received; the approaches used to verify, process, and accurately fill the requests; and the shipping and packing methods used to ensure the timely, safe, and intact arrival of clinical agents under conditions compatible with the appropriate clinical agent storage requirements. Discuss problems encountered with shipping and distributing investigational and commercial clinical agents both domestically and non-domestically, and the approaches employed to resolve these problems.

5. Documents and Regulations for Shipping Clinical Agents (SOW A.5)

Describe proposed plans and procedures for performing the following activities:

a. Generating all required shipping documents for shipping and distribution of clinical agents.
b. Researching required shipping regulations and documents for shipment of clinical agents to non-domestic countries.
c. Obtaining required import, export, and other regulatory documents from clinical research sites and DMID-approved testing laboratories.
d. Maintaining current licenses and permits for storing, handling, transporting, distribution of drugs, biologics, controlled substances, and clinical agents containing ethanol.

Include a discussion of common problems encountered in generating, researching, and obtaining such documentation and provide recommendations for solutions to such problems. Provide examples of shipping documents generated for the shipping and distribution of clinical agents to domestic and non-domestic sites within the past 5 years.

6. Tracking and Inventory Management of Clinical Agents (SOW A.6)

Describe proposed plans and procedures for tracking and inventory management of clinical agents, including the following:

a. Tracking, coding, and archiving information on all clinical agents received, acquired, stored and shipped to and from the CASR. Include a description of the proposed electronic inventory management system and the elements to be captured in that system to track receipt, location, and status of clinical agent.
b. Monitoring inventory to determine usage rates, expiration or retest dates, and acceptability of clinical agents with breaks in cold chain.
c. Performing physical inventories of clinical agents.

Briefly describe the physical inventories conducted within the past 5 years, including any protocol-specific inventories. Include a discussion of the results of the inventory and procedures used for reconciling discrepancies with computerized inventories.

7. Quarantine and Final Disposition of Clinical Agents (SOW A.7)

Describe the proposed onsite final disposition program, including procedures for: end-of –study reconciliation, identifying clinical agents to be removed from active stock at the repository or to be returned to the repository from domestic and non-domestic DMID-funded clinical research sites; notifying clinical research sites regarding final disposition of clinical agents; handling, processing, documenting, quarantine, and disposing of clinical agents that are returned, unused, expired, and/or recalled in accordance with all applicable local, state and Federal laws and regulations.

Provide a list of clinical agents that have been disposed in the past 5 years, including the reason for the disposal, length of quarantine, and origin of the clinical agent (i.e., current repository or returned). Document compliance with all U.S. and local public and occupational health, safety and environmental protection regulations.

8. Acquisition of Clinical Agents (SOW A.8)

Describe proposed plans and procedures for acquiring investigational clinical agents, commercial products, or other products required for the implementation of DMID-supported clinical trials. Include a discussion of the proposed approaches for performing non-clinical testing on the acquired clinical agents as outlined in Federal Regulations 21CFR610 and 21CFR211. Describe how the offeror will provide for additional *in vitro* and *in vivo* safety testing of acquired clinical agents.

Provide examples of non-clinical testing, including *in vitro* and *in vivo* safety testing, performed on clinical agents either at the offeror's facility or at proposed subcontractor facilities within the past 5 years. Discuss problems encountered during non-clinical testing and the strategies used to overcome the problems.

B. Clinical Specimens

1. Receipt and Short-Term Storage of Clinical Specimens from DMID-Funded Clinical Research Sites (SOW B.1)

Describe proposed plans and procedures for receiving clinical specimens from DMID-funded clinical research sites and providing short-term (up to 2 years) storage of clinical specimens in support of DMID-sponsored clinical research. Include a discussion of the plans and procedures for performing the following activities:

a. Arranging and coordinating handling and shipment of clinical specimens with the DMID-funded clinical research sites.
b. Receiving, inspecting, and reconciling discrepancies with shipping lists, clinical specimens and shipments received from domestic and non-domestic clinical research sites.
c. Tracking and recording contents and condition of shipments.
d. Storing clinical specimens at appropriate temperature conditions (-80ºC, -20ºC).

e. Ensuring continuous monitoring and documentation of storage temperatures and conditions for clinical specimens.
f. Receipt and processing of clinical specimen shipments.

Identify potential problems associated with the receipt and storage of clinical specimens and proposed solutions to overcome such problems. Describe the type (i.e., blood, serum, etc.), volume and clinical research source (i.e., domestic, non-domestic, clinical research sites, etc) of clinical specimens received and stored over the past 5 years. Describe the scope of clinical research from which the clinical specimens were obtained.

2. Aliquoting and Labeling of Clinical Specimens (SOW B.2)

Describe proposed plans and procedures for aliquoting and labeling clinical specimens for distribution to DMID-approved testing laboratories. Briefly describe aliquoting and labeling activities performed within the past 5 years. Include a discussion of the problems encountered and the methods and approaches implemented to resolve these problems.

3. Shipping and Distribution of Clinical Specimens (SOW B.3)

Describe proposed plans and procedures for shipping and distributing clinical specimens to DMID-approved testing laboratories. Describe existing procedures/approaches to ensure compliance with GLP and GCP regulations and domestic and non-domestic laws and regulations for the shipping and distribution of clinical specimens. Include a discussion of the plans and procedures for performing the following activities:

a. Shipping under conditions compatible with clinical specimen storage requirements, domestically and non-domestically.
b. Using appropriate types and quantities of packaging components to ensure the safe, intact arrival of clinical specimens.
c. Monitoring clinical specimen shipments with shipment receipt forms to confirm receipt and condition of clinical specimens.
d. Ensuring that shipments of clinical specimens are routinely received at domestic laboratories within 24 hours and at non-domestic laboratories within 3-5 calendar days.

Provide a list of domestic and non-domestic sites and laboratories to which clinical specimens were distributed over the past 5 years. Describe the types of requests for clinical specimens received, and the shipping and packing methods used to ensure the timely, safe, and intact arrival of clinical specimens under conditions compatible with the appropriate clinical specimen storage requirements. Discuss problems encountered with shipping and distributing clinical specimens, both domestically and non-domestically, and describe the approaches employed to resolve these problems.

4. Tracking and Inventory Management of Clinical Specimens (SOW B.4)

Describe proposed plans and procedures for tracking and providing inventory management of clinical specimens as follows:

a. Tracking, coding, and archiving information on clinical specimens received, stored, and shipped. Include a description of the elements to be captured in the proposed electronic inventory management system to track receipt, location, and status of clinical specimens.
b. Performing physical inventories of clinical specimens.

Briefly describe the physical inventories conducted within the past 5 years. Include a discussion of the results of the inventory and procedures for reconciling discrepancies with computerized inventories.

5. Final Disposition of Clinical Specimens (SOW B.5)

Describe the proposed onsite final disposition program, including plans and procedures for managing and documenting the final disposition of clinical specimens that have reached the two-year storage expiration date and of clinical specimens shipped to DMID-approved testing laboratories in a manner that meets all public and occupational health, safety and environmental protection regulations.

C. Overall Contract Requirements

1. Electronic Information Systems, Data Management, and System Security (SOW C.2)

a. Describe organizational experience in and provide a plan for maintaining and operating database information systems. Include a description of software and hardware used by the offeror and any proposed subcontractors over the past 5 years for projects of the same or similar scope, complexity and requirements. Include a discussion of problems encountered in the maintenance, operation and security of information systems used for the same or similar purposes and the approaches implemented to resolve these problems. Discuss plans to investigate new and improved technologies to enhance the efficiency and ease of use of the existing Clinical Agent and Clinical Specimen Repository Inventory Management Database System.
b. Describe organizational experience in and provide a plan for coordinating clinical agent and clinical specimen repository functions with other clinical research support contractors with respect to: (i) verifying regulatory status for each DMID IND and IDE prior to receipt of clinical agents from suppliers; (ii) verifying receipt of essential regulatory documents and tracking clinical site protocol status prior to shipping clinical agents to clinical research sites; and (iv) identifying and tracking clinical specimens received from DMID-funded clinical research sites prior to shipping clinical specimens to DMID-approved testing laboratories. Include a discussion of proposed methods for achieving effective and efficient coordination, anticipated problems, and approaches to resolving anticipated problems.
c. Describe organizational experience with NIH Information Security requirements and familiarity with DHHS Automated Information Systems

Security Programs. Provide a proposed plan to meet requirements for information security.

2. Internal Training of CASR Personnel (SOW C.3)

   Describe plans for providing and documenting internal training for Contractor and subcontractor personnel spanning the breadth of contract requirements and including: safety measures for handling clinical agents and clinical specimens and proper procedures for the receipt, storage and shipping of all clinical agents and clinical specimens used at DMID-funded clinical research sites and DMID-approved testing laboratories. Provide a list of the SOPs that will be established and maintained for training purposes.

3. Quality Assurance/Quality Control (SOW C.4)

   a. Provide a proposed Quality Assurance/Quality Control (QA/QC) Plan to standardize contract processes to ensure that the conduct of all activities complies with domestic and non-domestic regulations and requirements. The proposed QA/QC Plan should include: (i) a list of SOPs for all operations outlined in the Statement of Work, including procedures for maintaining version control of all SOPs; (ii) SOP template; (iii) plans for initial and annual training of Contractor and subcontractor staff with respect to all operating procedures; (iv) procedures for maintenance and validation status of equipment and computer software; (v) plans for maintenance of facility accreditations; (vi) plans for documenting adherence to all applicable requirements and guidelines; and (vii) record retention and storage procedures and plans to ensure the accuracy and integrity of tracking processes for repository functions.
   b. Describe proposed plans to arrange for site visits and accommodate independent audits to evaluate Contractor and subcontractor facilities for compliance with domestic and non-domestic laws and regulations, FDA regulations and guidances, including those required to meet GLP, cGMP and GCP standards, DMID policies, and the terms of the contract.

4. Initial and Final Transition (SOW C.6)

   Provide proposed plans for the initial and final transition of contract materials, databases and equipment, including approaches to ensure that there is no loss of time or interruption to the conduct of ongoing DMID-funded clinical research and clinical research in development during the transition period. Discuss the proposed staffing requirements for the initial and final transition, including number and type of personnel required, as well as proposed percent effort. Also provide proposed plans for the training of Contractor and subcontractor personnel with respect to all aspects of initial and final transition activities.

SECTION 4: FACILITIES, EQUIPMENT, SAFETY, TRAINING, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment and other resources necessary to carry out the Statement of Work, including:

A. Location and features of the proposed facility(ies) including a detailed description of equipment and resources dedicated to the project for the offeror and any proposed subcontractors.

B. Detailed floor plan of the proposed facility showing the location of equipment, clean room(s), offices, shipping docks, freezers, refrigerators, quarantine areas, storage areas, packaging areas, labeling areas, and processing, returns, and archival space.

C. Information to document the ability of the offeror and any proposed subcontract to provide::

For clinical agents and clinical specimens:

1. 2,500 cubic feet of storage at controlled temperature, USP.
2. 10,000 cubic feet of storage at 2 to 8°C.
3. 14,000 cubic feet at -20°C for clinical agent storage/ 400 cubic feet at -20°C for clinical specimen storage.
4. 1,500 cubic feet at -80°C for clinical agent storage/ 400 cubic feet at -80° for clinical specimen storage.
5. Suitable areas for labeling, packaging and repackaging of clinical agents and clinical specimens.
6. Suitable areas for quarantine of clinical agent at the proper storage temperature.
7. 24-hour a day temperature monitoring to record and ensure maintenance of appropriate storage temperature.
8. Automatic, safe, continuous and reliable supply of power.
9. Humidity controlled and monitored conditions and protection of clinical agents and clinical specimens sensitive to carbon dioxide or light.
10. 24-hour a day, 7 days a week, physical and electronic security for the facility, clinical agents, clinical specimens, and computer related systems.

D. Information regarding ownership or lease of the facility(ies) demonstrating facility availability at the initiation of, and for the duration of the contract.

E. Plans and procedures to be utilized for complying with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and other hazardous agents and materials.

F. Documentation of compliance with cGMP, GLP and GCP.

G. Provisions for ensuring safe facilities, equipment and resources and for conduct of work in accordance with biosafety guidelines.

H. Maintaining a facility compliant with the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135) and with Title 21, Code of Federal Regulations, Part 210 and 211.

I. Plan for transfer of clinical agents and clinical specimens to appropriate storage conditions in the event of power failure, fire, flood, or other occurrences capable of damaging clinical agents of clinical specimens.

J. Handling controlled substances in compliance with U.S. Drug Enforcement Agency requirements.

SECTION 5: SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity carried out by the offeror and any proposed subcontractors over the past 5 years.

A. Principal Investigator (PI)

The Principal Investigator (PI) shall document training, education, expertise, experience and qualifications with respect to the following:

1. Management and operation of a clinical agent and clinical specimen repository in accordance with applicable cGMP, GLP and GCP regulations including: (i) receipt and storage of clinical agents and related products from domestic and non-domestic product suppliers; (ii) processing, labeling, packaging, and shipping of clinical agents and related products to clinical research sites and DMID-approved testing laboratories; (iii) acquisition and non-clinical testing of clinical agents and related products; (iv) receipt and storage of clinical specimens from domestic and non-domestic clinical research sites; (vi) processing, labeling, packaging, and shipping of clinical specimens to clinical research sites and DMID-approved testing laboratories; and (vii) monitoring of inventories and disposing of expired, unused, recalled, and returned clinical agent, related product, or clinical specimen.

2. Coordination, management and QA/QC for projects of similar size and complexity including management, oversight and system security for databases and information systems for tracking and reporting repository activities.

3. Identification and resolution of problems and issues, prioritization of projects, and identification of qualified personnel to carry out repository functions.

4. Interaction with clinical research staff at sites, industry and/or the NIH including coordination with other clinical research support contractors.

5. Design and conduct of training activities related to repository safety and technical procedures.

B. Other Scientific and Technical Personnel

Document the training, education, expertise, experience and qualifications of the other proposed scientific and technical personnel of the offeror and all proposed consultants and subcontractors in the following areas:

1. *Repository technicians* for: receipt, storage, aliquoting, labeling, packaging, repackaging, shipping, tracking, inventory management and disposing of clinical agents and clinical specimens.
2. *Laboratory technicians experienced in performing non-clinical testing of acquired clinical agents.*
3. *Information technology personnel* for: the maintenance and operation of existing databases, back-up systems and system security procedures; interface with other clinical research support contractors; evaluation of new and improved technologies and implementation of system upgrades/modifications; and programming and set-up of repository information systems and providing IT user support.
4. *Quality assurance/quality control staff* for: ensuring the conduct of all repository activities complies with domestic and non-domestic regulations and requirements; maintaining version control of SOPs, ensuring and documenting training for Contractor and subcontractor personnel; ensuring maintenance and documentation of equipment and facilities; and ensuring the accuracy and integrity of tracking processes for repository activities.
5. *Trained and certified staff*: for ensuring compliance with domestic and non-domestic regulations, and handling biohazardous materials

SECTION 6: PROJECT MANAGEMENT

A. Provide a plan for project organization, staffing, and management in relation to the implementation, conduct, monitoring and completion of contract requirements. Include a detailed description of the responsibilities and the level of effort for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel. If consultants and/or subcontractors are to be used, include a plan to manage and coordinate consultant and/or subcontractor(s) efforts. Include a chart of the proposed organizational/management structure for the project.

B. Describe project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

C. Outline how the PI will communicate and interact with the Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

D. Provide a plan for how the Contractor and any proposed subcontractors will safeguard confidentiality and intellectual property of data and materials provided to them by third parties or the United States Government, as well as data generated during the contract.

SECTION 7: OPTIONS

Each Option should be presented as a separate part of the Technical Proposal and clearly identified as such. This portion of the Technical Proposal will be included in the total page limitation. For each option, provide a discussion of how the Offeror proposes to plan for and implement each option.

Option 1: Increased Clinical Specimen Capacity

Describe how clinical specimen capacity of the CASR will be increased, including: (i) a description of the anticipated additional capacity required; (ii) proposed approaches/procedures to accommodate the increased clinical specimen capacity; (iii) facilities, equipment and other resources to be made available; (iv) projected timeline for the implementation of increased clinical capacity at the CASR, and (v) if additional staff will be required.

Option 2: Increased Length of Time for Storage of Clinical Specimens

Describe how the storage of clinical specimens beyond the short-term period (two years) as outlined in the Statement of Work for the basic requirement will be accommodated, including: (i) proposed approaches/procedures to accommodate the increased clinical specimen storage period; (ii) facilities, equipment and other resources to be made available; and (iii) projected timeline for the implementation of the additional storage requirement and (iv) if additional staff will be required.

SECTION 8: OTHER CONSIDERATIONS

Section L of the RFP provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the RFP for specific requirements. Read each section below carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

1) Care of Live Vertebrate Animals

Section L of the RFP specifies the minimum documentation requirements for Animal Welfare compliance. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Animal Welfare issues.

2) Biological Agents or Toxins

The Technical Proposal should include a plan for biohazard safety and security requirements.

3) Sharing Research Data (Plan)

Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for Data Sharing as required by this RFP.

4) Information Technology (IT) Systems Security

Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical

Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP.

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

In addition to the format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this Appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the statement of work, all reference material provided as appendices and attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET (use form NIH 2043 identified in Section J)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS

A. Technical Cost Assumptions

1. *Ongoing Activities at contract award - assume responsibility for the following:*

   a. *Clinical Agents:*

      i. A total of 150 different clinical agents consisting of 550,000 total units, requiring the following storage capacity:

         - -194^{o}C, 2-4 tanks with a capacity to hold approximately 25,000 vials
         - -80^{o}C, (approximately 1,000 cu. ft.)
         - -20^{o}C, (approximately 10,000 cu. ft.)
         - 2 to 8^{o}C, (approximately 5,000 cu. ft.)
         - Controlled room temperature, (approximately 1,500 cu. ft.)

      ii. Receipt and storage of 4 different clinical agents from suppliers consisting of 4000 total units.

iii. Labeling and repackaging of 4 different clinical agents consisting of 1000 total units to be labeled "Not for Human Use."

iv. Shipment of 5 different clinical agents consisting of 500 total units in 20 separate shipments. Assume eighteen shipments will be overnight to domestic sites and two shipments will be to non-domestic sites for 3-5 calendar day delivery.

b. *Clinical Specimens*:

i. A total of 400,000 clinical specimens requiring the following storage capacity:

- -80^{o}C, (approximately 300 cu. ft.)
- -20^{o}C, (approximately 300 cu. ft.)

2. *New activities <u>during the contract period of performance – assume the following</u>:*

a. *Receipt and Storage of Clinical Agents:* Receipt of 175 shipments of clinical agents consisting of 50,000 total units per year requiring the following storage capacity:

- -194^{o}C, 4 - 6 tanks with a capacity to hold approximately 50,000 vials
- -80^{o}C, (approximately 1,400 cu. ft.)
- -20^{o}C, (approximately 14,000 cu. ft.)
- 2 to 8^{o}C, (approximately 10,000 cu. ft.)
- Controlled room temperature, (approximately 2,500 cu. ft.)

b. *Labeling, Packaging, and Repackaging of Clinical Agents:* Labeling and packaging of 40 different clinical agents consisting of 10,000 total units per year. Repackaging of 3 different clinical agents per year into patient-specific, unit of use packaging such as blister packaging consisting of 450 total units.

c. *Shipping Preparation:* Validation of 6 different shipment packing configurations per year.

d. *Shipping and Distribution of Clinical Agents.* Include in your business proposal an amount of $257,750 per year for packaging and shipping. Escalate this cost annually based on the current Consumer Price Index. Assume that approximately 300 shipments consisting of 17,000 total units will be made each year.

i. Assume that 20% of clinical agent shipments will be to non-domestic sites and must be delivered within 3 to 5 calendar days.
ii. Assume that 80% of clinical agent shipments will be to domestic sites and must be delivered within 24 hours.

e. *Inventory Management.* The conduct and completion of annual physical inventories of clinical agents and clinical specimens.

f. *Final Disposition of Clinical Agents. Q*uarantine and disposal of 10 different clinical agents per year at the CASR consisting of 1000 total units.

g. *Acquisition of Clinical Agents*: Include in your business proposal an amount of $150,000 per year for the purchase of clinical agents that cannot be obtained through donation. Escalate this cost annually based on the current Consumer Price Index. Include $50,000 per year for *in vitro* safety testing and $50,000 per year for *in vivo* safety testing to be conducted on acquired clinical agents.

h. *Receipt and short-term storage of Clinical Specimens:* Receipt of 180 shipments of clinical specimens consisting of 180,000 total units per year requiring the following storage capacity:

- -80^{o}C, (approximately 400 cu. ft.)
- -20^{o}C, (approximately 400 cu. ft.)

i. *Aliquoting, Labeling, and Distribution of Clinical Specimens:* Assume that 10 different DMID-funded multi-center clinical trials per year will require the aliquoting, labeling and distribution of clinical specimens consisting of 25 shipments totaling 20,000 units.

i. Assume that 5% of clinical specimen shipments will be to non-domestic sites and must be delivered within 3-5 calendar days.
ii. Assume that 95% of clinical specimen shipments will be to domestic sites and must be delivered within 24 hours.

j. *Final Disposition of Clinical Specimens*: Assume final disposition of 500 clinical specimens per year.

3. *Initial and Final Transition*: Include a separate breakdown of all costs associated with the Initial and Final Transition.

B. Travel

1. *Contract Initiation Meeting*

Assume travel for the Principal Investigator (PI) and 4 key Contractor staff to participate in a one-day contract initiation meeting, to be held in the Bethesda, Maryland area.

2. *Weekly Progress Meetings*

Assume travel for the PI and 4 key Contractor/subcontractor personnel to attend two (2), 2-hour meetings per month at the offices of DMID.

3. Annual Meetings

Assume travel for the PI and 4 key Contractor/subcontractor staff to participate in annual 2-day meetings, to be held in the Bethesda, Maryland area.

4. *Other Meetings*

   a. DMID-Funded Clinical Investigator Meetings: Assume travel for one key Contractor staff to participate in 4 one-day protocol-specific investigator meetings per year. Assume that two of these meetings will be within a 50 mile radius of Washington, DC and that two of these meetings will be held outside of the Washington, DC area within the U.S.

   b. Annual Meetings of DMID-Funded Clinical Research Networks: Assume travel for 2 key Contractor/subcontractor staff to participate in 4 one-day investigator meetings per year. Assume that these meetings will be within a 50 mile radius of Washington, DC.

5. *Training for CASR personnel*

   Include $4000 per year for training of CASR personnel.

C. Other

In order to implement and utilize the Clinical Agent Repository Inventory Management (CARIM) database system, the Contractor shall include the costs for purchasing the following servers and software with the following specifications:

Web Server

Software: Microsoft Windows 2003 Server, IIS 6.0, Adobe Coldfusion MX 7.02, MacAfee Antivirus, SSL 2.0, CTi.Crypto20.DLL, CTi FolderWatcher

Hardware: Dell PowerEdge 1750, 1024 Meg Memory, 40 GIG HD space

Database Server

Software: Microsoft Windows 2003 Server, Microsoft SQL Server 2000, Microsoft Outlook Client, SSL 2.0, CTi.Crypto20.DLL

Hardware: Compaq Proliant DL380 2 GB memory, 30 GB HD space

Backup Server

*Software***:** Microsoft Windows 2003 Server, IIS 6.0, Adobe Coldfusion MX 7.02, SSL 2.0, CTi.Crypto20.DLL

Hardware: Compaq Proliant DL380 2 GB memory, 30 GB HD space

Mail Server

*Software***:** Microsoft Windows 2003 Server, ActiveMail Mail Server, SSL 2.0

*Hardware***:** Compaq DL380 G4 3 36.8 gig 1500 RPM drives, 2 gig memory, and 2.8 Intel processors

SECTION 4 - Options

A separate cost proposal must be prepared for each option.

Option 1: Increased Clinical Specimen Capacity

Assume the clinical specimen capacity requirements will triple.

Option 2: Increased Length of Time for Storage of Clinical Specimens

Assume the length of time for storage of clinical specimens will increase to the period of performance of the contract.

Option 3: Extension of Base Period of Performance

Assume the services provided for in the base period will continue for an additional two (2) years.

SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1) Small Business Subcontracting Plan

Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2) Extent of Small Disadvantaged Business Participation

Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

3) Past Performance Data, including references

Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

ADDITIONAL RFP-SPECIFIC MATERIALS

NIAID DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES: CLINICAL AGENT AND SPECIMEN REPOSITORY RFP-NIH-NIAID-DMID-08-26

☒ The below RFP-Specific Materials are applicable to this solicitation.

CURRENT DMID CLINICAL RESEARCH PROGRAMS

Vaccine and Treatment Evaluation Units (VTEUs)

Established in 1962, the NIAID Vaccine and Treatment Evaluation Units (VTEUs) are composed of university research hospitals across the United States that conduct Phase 1, 2, 3 and 4 clinical trials to evaluate candidate vaccines and therapeutics for a broad range of infectious diseases, including potential agents of bioterrorism. The VTEU program currently consists of the seven contracts listed below. Recompetition of the VTEU contracts is underway and awards are anticipated in early FY 2008 (see Request for Proposals at http://fs1.fbo.gov/EPSData/HHS/Synopses/3465/NIH-NIAID-DMID-08-03/NIAID-DMID-08-03RFP.pdf)

Current VTEU sites:

Baylor College of Medicine	N01-AI-25465
Cincinnati Children'sHospital Medical Center	N01-AI-25459
Harbor UCLA Medical Center	N01-AI-25463
Saint Louis University	N01-AI-25464
University of Maryland, Baltimore	N01-AI-25461
University of Rochester	N01-AI-25460
Vanderbilt University	N01-AI-25462

DMID Viral and Respiratory Pathogen Research Unit (VRPRU)

The VRPRU (Contract No. N01-AI-30039) was awarded to Baylor College of Medicine in 2003. This multidisciplinary network supports pre-clinical studies designed to provide proof-of-concept data to accelerate progression of candidate products to clinical evaluation. This contract also supports Phase I and Phase II clinical trials of vaccines and therapeutics against selected human viral respiratory pathogens, including influenza, development of relevant immunological assays, and human challenge studies with influenza viruses.

DMID Bacterial and Respiratory Pathogen Research Units (BRPRU)

The BRPRU (Contract No. N01-AI-30040) was awarded to the University of Iowa in 2003 to conduct preclinical and clinical studies including Phase 1 and Phase 2 clinical trials of vaccines, therapeutics, diagnostics, other biologics and drugs as preventive and therapeutic measures against bacterial respiratory pathogens. The focus is on translational and clinical research.

Malaria Vaccines: Clinical Research and Trial Sites in Endemic Areas

This contract (Contract No. N01-AI-40016) was awarded to Noguchi Memorial Institute for Medical Research on June 1, 2004. Subcontracts are currently in place in Ghana and Burkina Faso, through which multiple Phase 1 and Phase 2 malaria vaccine trials take place.

The Collaborative Antiviral Study Group (CASG)

The CASG is a multi-center activity supporting clinical trials of therapies for viral infections other than HIV. The Principal Investigator and the core infrastructure are located at the University of Alabama at Birmingham.

DMID-FUNDED CLINICAL RESEARCH SUPPORT SERVICES CONTRACTS

DMID Clinical Trials Management Support Contract

PPD Development, LP, located in Wilmington, NC, provides clinical trials management support to DMID and DMID investigators. PPD Development specific responsibilities include the following:

A. Clinical site assessment, evaluation of clinical sites for clinical research feasibility and capacity;
B. Clinical site preparation and clinical trial operations assistance; study document preparation and review;
C. Establish and assist clinical sites with internal quality control and quality assurance;
D. Provide Good Clinical Practice training;
E. External clinical site monitoring, including site initiation, interim and close-out visits and quality audit visits;
F. Centralized pharmacovigilance and safety monitoring; and
G. Information and document management through web-based systems.

The Clinical Trials Management (CTM) contractor provides to DMID a centralized database developed from commercial software. The CTM contractor maintains the database and the data held in the database for DMID-funded clinical trials and clinical studies. Information stored for tracking and reporting purposes includes clinical site information, clinical protocol information, inventory of essential documents for clinical sites, and schedule of clinical site visits. The CTM archives clinical site essential documents and protocols in readable pdf format on a secure website.

DMID Data Coordinating Center for Clinical and Epidemiologic Studies in Infectious Diseases

EMMES Corporation, located in Rockville, MD, provides several services for DMID-supported clinical research programs, including the following:

A. Provides statistical leadership and clinical trial design expertise for the development of protocols and the analysis of study data;
B. Establishes and administers data collection, management, quality assurance and reporting systems;
C. Provides adverse event safety reporting system and reconciles with the pharmacovigilance (SAE) system maintained by the CTM contractor;
D. Provides detailed record maintenance and timely reporting;
E. Provides an inventory and tracking system for study specimens; and
F. Collaborates with DMID, DMID-supported research groups, individual Principal Investigators and contractors.

The Data Coordinating Center contractor provides a password-protected web site for DMID-funded clinical investigators and DMID staff that contains information relating to various DMID-sponsored clinical studies. The web site provides access to the study protocols, source documents, reports, manuals of procedure, rosters, and other relevant study materials. Also included is a link to AdvantageEDCSM, the Internet data entry system used to submit and audit data collected in the studies.

In addition, the Data Coordinating Center contractor has designed, developed and validated a secure, state-of-the-art data collection and computer-based data and study management system and related procedures, including the capacity to customize as necessary for particular studies. The system provides for receiving, entering, verifying, processing, editing (including within and between form validity, logic and consistency checks), updating, correcting, storing, tracking, retrieving and analyzing data. The system allows management of all study data from the various clinical and laboratory sites, adverse event tracking across studies, study logistics, study status reporting and clinical project tracking.

This contract is being recompeted for award in FY 2008. A copy of the Request for Proposals for this initiative, the Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases, can be found at: http://www.niaid.nih.gov/contract/archive2008.htm.

DMID Regulatory Affairs Support Contract

Currently awarded to Fisher BioServices Corporation, located in Rockville, MD., the DMID Regulatory Affairs Support contract provides regulatory and clinical agent and clinical sample repository support services, including:

A. Preparation and maintenance of Investigational New Drug (IND) applications;
B. Preparation and maintenance of Investigational Device Exemptions (IDE)
C. Consulting and auditing for manufacturers of DMID investigational products;
D. Management and operation of a clinical agent repository for distribution and tracking of clinical agents; and
E. Management and operations of a clinical specimen repository for DMID-supported clinical trials.

The current DMID Regulatory Affairs Support contractor utilizes two DMID-owned database management systems, the Clinical Agent Repository Inventory Management (CARIM) system and the Human Subjects Research Oversight Accountability Database

(HSROAD). HSROAD is a centralized web-based IND/IDE management database that captures and tracks a variety of regulatory-related data for DMID, including: 1) the progress of IND/IDE clinical trials from concept through protocol implementation, modification, and final reporting; 2) the documentation of receipt and dates of filing regulatory documents to the IND/IDE; 3) name and contact information for pertinent individual sites and investigators; 4) the products and lot numbers being used in DMID-funded clinical research; 5) the receipt of all essential documents to allow shipping of product to clinical sites, and 6) electronic ordering of clinical agents from DMID-funded clinical research sites.

CARIM is a web-based clinical agent inventory management database system for the receipt, processing, tracking, shipping, inventory control, and activity report-generation, of clinical agents used in DMID-funded clinical research. CARIM consists of several major modules and an administrator module. The major modules contain user interfaces, processes, and a centralized data repository to capture and manage the data related to the management of a clinical agent inventory. The CARIM database was developed following best practices for relational database design, data normalization, and development; and is deployed on the Microsoft SQL Server 2000 database server. The Web server software is Microsoft's Internet Information Services 6.0 (IIS). The ColdFusion Enterprise MX application server is used to connect the Web application to the database and to provide dynamic content for the browser-based CARIM application. All the architecture is based on the Microsoft Windows 2003 server software. The application is targeted for users with Microsoft's Internet Explorer version 5.0 or greater, or Netscape's Navigator version 8.0 or greater.

The HSROAD and CARIM system descriptions can be found at: http://www.niaid.nih.gov/research/resources/DMIDClinRsrch/links.htm.

The regulatory affairs support contract currently being performed by Fisher BioServices Corporation is being recompeted as a separate contract for award in FY 2008. A copy of the Request for Proposals can be found at: http://www.fbo.gov/spg/HHS/NIH/NIAID/RFP%2DNIH%2DNIAID%2DDMID%2D08%2D05/listing.html